dr. Respati W. Ranakusuma, SpTHT-KL
Clinical Epidemiology & Evidence-Based Medicine Unit, Dr. Cipto Mangunkusumo Hospital – Faculty of Medicine Universitas Indonesia

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

Oral prednisolone for acute otitis media in children: a pilot pragmatic randomised open-label single-blind controlled study (OPAL study)

[Steroids for middle ear infection in children]

Invitation

You are invited to participate in a research study into the use of steroids (prednisolone) or an anti-inflammatory drug for middle ear infection in children.

The study is being conducted by Dr. Respati W. Ranakusuma, an otorhinolaryngologists and a researcher at the Clinical Epidemiology and Evidence-Based Medicine (CEEBM) Unit Dr. Cipto Mangunkusumo Hospital–Faculty of Medicine Universitas Indonesia. This is part of an international collaborative study between CEEBM CMH-FMUI and the Centre for Research in Evidence-Based Practice (CREBP), Faculty of Health Sciences and Medicine Bond University, Queensland, Australia.

Before you decide whether or not you wish to participate in this study, it is important for you to understand why the research is being done and what it will involve. Please take the time to read the following information carefully and discuss it with others if you wish.

1. **What is the purpose of this study?**
   The purpose is to investigate whether steroids, as an alternative treatment, will reduce ear pain and other symptoms in children with acute or recent (less than 48 hours) middle ear infection. This study is part of a doctoral project at the CREBP Bond University, Queensland, Australia. As this is a pilot study, we also want to know your experience during the study. For example, the obstacles you found in giving the steroid to your child or completing the symptom diary daily.

2. **Why have my child and I been invited to participate in this study?**
   Your child and you have been invited to participate in this study because your child age ranges between six months to 12 years and having symptoms and signs of acute middle ear infection, such as ear pain in the past 48 hours, or holding or tugging her/his ear more frequently, more irritable, show lack of playfulness and/sleep in a young age (baby). If visible, from the ear examination, the ear drum(s) will show redness or yellowish, bulging, or discharge.

3. **What does participation in this study involve?**
   If you agree to participate in this study, your physician will ask you more questions regarding the history of your child's previous infection, allergy, and the severity of the symptoms (e.g. ear pain, fever, disruption of daily activities). As only your child and you as the parents know the best of how severe the symptoms are, we will ask you to show the severity of the symptoms using two tools. The first tool is called visual analogue scale. It is a 10-cm horizontal line, whereas the left end of the line represents 'no pain' and the right end represents 'the most painful'. We will ask you to draw a vertical line across this line at the point that represents how bad

the symptom that your child has been experiencing. The second tool is called acute otitis media – the severity of symptoms (AOM-SOS) that consisted of seven questions. You will be asked to choose one of the severity scales ('no', 'a little', or 'a lot') that corresponds to seven particular symptoms (i.e. tugging/rubbing the ears, crying more, more irritable, lack of sleep, playfulness, and appetite, and fever). Whilst you providing your best answers using these tools, your physician will also teach you to complete the symptom diary that consists similar questions that your physician has been obtained from you. This will help you in completing the symptom diary during the study which will help us to investigate the effect of the steroid in improving your child' ear pain and other symptoms due to acute middle ear infection. After that, your attending nurse and physician will examine your child's general status (i.e. body weight, height, body temperature, blood pressure) and ear-nose-throat status. From there, we will check the condition of your child's middle ear using a tool called tympanogram. This is a painless procedure to detect whether there is a fluid in your child's middle ear. From there, you will meet a nurse who will allocate your child whether she/he will receive the steroid (treatment group) or not receive the steroid (control group). Your child has 50% chance for being allocated to receive the steroid. We will do this process randomly where no one can predict in which group your child will be allocated to. This process will require 15 to 30 minutes because the nurse has to access this information from the website or calling the research team. If your child receives the steroid, she will give you a prescription for your study medication. You will give the prescription to the pharmacy at that hospital. The pharmacist will prepare your study medication by crushing the tablets, mixing it with sweeteners, and packing the study medication in a daily paper-package (you will receive five daily packages). The nurse will give an instruction to give a medication to your child every morning, once daily for 10 to 30 milligrams depends on your child's age, for five days. You can give this medicine with a glass of milk or juice, or with a small amount of soft food such as honey, jam, or yoghurt. She will tell you what to do if your child vomits after taking a drug or experiences any effects. She also will ask you to keep the confidentiality of the treatment that your child receives from your physician and audiologist. The whole process will require 60 to 120 minutes depends on the cooperativity of your child. We will ask you to come after two and seven days after your visit. On these visits, we will investigate whether the steroid will help reducing the ear pain and other relevant symptoms and whether it give unfavorable effects. During these visits, we will ask you to bring the symptom diary and the left-over drug so we can check your child' condition. We also will ask you to come after one and three months to see whether during these time, your child experiences a new episode of acute middle ear infection. After these four additional visit after this visit, we consider that your child has completed the study.

Any information obtained in connection with this research project that can identify you child and you will remain confidential. If you agree to participate in this study, you will be asked to sign the Participant Consent Form.

4. **What if I do not want to take part in this study, or if I want to withdraw later?**

Participation in this study is voluntary. It is completely up to you or both of you and your child if you child aged 12 years, whether or not you participate. If you decide not to participate, it will not affect the treatment your child receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for your child. However, it may not be possible to withdraw your data from the study results if these have already had your identifying details removed.

5. **How is this study being paid for?**
   The study is being for by Dr. Respati W. Ranakusuma, ORL which is supported by self-funded.

6. **Are there risks to my child in taking part in this study?**
   The foreseeable risks in taking part in this study are the bitter taste of prednisolone tablets and some potential side effects of the steroids. Pharmacist will mix the crushed tablets with sweeteners and we will also provide honey to be mixed with the medication. The common potential side effects of steroids are nausea, vomiting, abdominal pain, nervousness, mood swings, headache, increased blood sugar and blood pressure, weight gain, etc. Growth disorder could be one of the side effects however it usually occurs on the longer use of the steroids. We cannot predict whether your child will have one of these effects or not at all.

   You may feel that the whole process of this study will take longer time compared to usual doctor visit due to collection of information and additional examination that will be conducted in this study. It may add some work for you to complete a symptom diary daily for the next 14 days. However, this is very important to be able to assess the day-by-day progress of your child with or without the steroids. Other potential inconveniences that your child and you may experience from this study are during the tympanometry examination and the follow-up visits (four additional visits are required in this study). Even though tympanometry is a painless procedure, we expect that your child will sit still for at least 10 minutes where she/he will hear a ringing sound and a pressure sensation during the process.

7. **What happens if my child suffers injury or complications as a result of the study?**
   If you require treatment or suffer loss as a result of the negligence of any of the parties involved in the study, you may be entitled to compensation; the cost of your treatment would have to be paid out of such compensation.

8. **Will I benefit from the study?**
   This study aims to further medical knowledge and may improve future treatment of acute middle ear infection (especially in mild cases where usually antibiotics are being prescribed), however, this study may not directly benefit you.

9. **Will taking part in this study cost me anything, and will I be paid?**
   Participation in this study will not cost you anything, nor you will be paid. You will be reimbursed for reasonable travel expenses to the amount of $15. We will cover the registration and consultation fees for the additional four follow-up visits to the hospital. We will also provide a study bag for your child.

10. **How will my confidentiality be protected?**
    Any identifiable information that is collected about your child in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researchers named above will have access to your details and results that will be held securely at the CEEBM CMH – FMUI. We will use your personal contact data, such as mobile number, home address, and e-mail address for the

following study purposes: (1) sending a reminder text message; (2) for home visit at Day-14 to collect the third mini-booklet of symptom diary; and (3) sending the result summary at the end of the study.

11. What happens with the results?

If you give us your permission by signing the consent document, we plan to discuss/publish the results for the monitoring and safety purposes (by the Human Research Ethics Committee, data monitoring and auditing committee, if necessary) and for publication in peer-reviewed journals or presentation at conferences or other professional forums. In any publication, information will be provided in such a way that you cannot be identified.

12. What should I do if I want to discuss this study further before I decide?

When you have read this information, your physician as one of the researchers, will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact Dr. Respati W. Ranakusuma, ORL by phone on +62 8111 012 185.

13. Who should I contact if I have concerns about the conduct of this study?

This study has been approved by the Medical Ethics Committee FMUI and the Bond University's Human Research Ethics Committee (BUHREC) Bond University, Queensland, Australia. Any person with concerns or complaints about the conduct of this study should contact Dr. Respati W. Ranakusuma on +62 8111 012 185, or email OPAL.study@bond.edu.au.

The conduct of this study at (please circle the answer that representing your hospital) the Dr Cipto Mangunkusumo Hospital / Persahabatan Hospital / Gatot Subroto Army Hospital / Antam Medika Hospital / Cempaka Putih Islamic Hospital / Proklamasi ENT Hospital / Hermina Bekasi Hospital, has been authorised by the the Health Agency for the Province of DKI Jakarta and the Directorate-General for Politics and General Government – The Ministry of Internal Affairs Republic Indonesia.

Thank you for taking the time to consider this study. If you wish to take part in, please sign the attached consent form. This information sheet is for you to keep

dr. Respati W. Ranakusuma, SpTHT-KL
Clinical Epidemiology & Evidence-Based Medicine Unit, Dr. Cipto Mangunkusumo Hospital – Faculty of Medicine Universitas Indonesia

CONSENT FORM

Oral prednisolone for acute otitis media in children: a pilot pragmatic, randomised, open-label, single-blind study (OPAL study)

[Steroids for middle ear infection in children]

1. I, _____
   of _____
   agree to participate in the study described in the participant information statement set attached to this form.
2. I acknowledge that I have read the participant information statement, which explains why my child has been selected, the aims of the study, and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.
3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm my child might suffer as a result of my child participation and I have received satisfactory answers.
4. I understand that I can withdraw from the study at any time without prejudice to my relationship to my physician and the _____ Hospital.
5. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
6. I understand that I have any questions relating to my participation in this research, I may contact Dr. Respati W. Ranakusuma, ORL on telephone +62 8111 012 185, who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participation Information Statement.

Complaints may be directed to the OPAL Study Support Office at the Clinical Epidemiology and Evidence-Based Medicine Unit, Dr Cipto Mangunkusumo Hospital – Faculty of Medicine Universitas Indonesia, Building H Dr Cipto Mangunkusumo Hospital, Diponegoro 71, Jakarta 10430, Indonesia (phone +62 21 316 1760, email OPAL.study@bond.edu.au).

Signature of participant or the parent	**Name**	**Date**
_____	_____	_____
Signature of witness	**Name**	**Date**
_____	_____	_____

For each question, please tick (✓) your answer on O or write you answer on _____

Signature of investigator	**Name**	**Date**
_____	_____	_____

REVOCATION OF CONSENT

Oral prednisolone for acute otitis media in children: a pilot pragmatic, randomised, open-label, single-blind study (OPAL study)
[Steroids for middle ear infection in children]

I hereby wish to WITHDRAW my consent to participate in the study described above and understand that such withdrawal WILL NOT jeopardise any treatment or my relationship with the _____ hospital or my medical attendants.

Signature of participant or the parent	**Name**	**Date**
_____	_____	_____

The section for Revocation of Consent should be forwarded to Dr. Respati W. Ranakusuma, ORL at the Clinical Epidemiology and Evidence-Based Medicine Unit, Dr Cipto Mangunkusumo Hospital – Faculty of Medicine Universitas Indonesia.

STUDY RECRUITMENT LOG BOOK

Nurse Name / ID :	Protocol : Oral prednisolone for acute otitis media in children: a pilot pragmatic, randomised, open-label, single-blind, controlled study (OPAL study)	Site / Hospital ID :

Study Registration ID	Patient's Name	Date Screened	Q1. Does your child experience ear pain in the past 48 hours? (YES or NO)	Q2. Has your baby been tugging or rubbing her/his ear(s) and been more irritable or fussy or crying more than usual over the past 48 hours (YES or NO)	Q3. Has your child been experiencing ear discharge in the past 48 hours? (YES or NO)	Went on the study? (YES or NO)	If YES, what is the Randomisation ID	If NO, please tell us reason not on the study below		
								Not eligible (YES or NO)	Did not give consent (YES or NO)	Was not approached (YES or NO)

For each column, please write your answer or choose 'Y' for YES or 'N' for NO

REGISTRATION ID | | | |

STUDY REGISTRATION FORM

PATIENT'S INFORMATION

Patient's name	_____
Place and date of birth	_____ , _____
Education	O None O Pre-school O Elementary school O Middle junior school O High school
School attending hours	O once a week from: _____ am/pm to _____ pm/pm O Twice a week from: _____ am/pm to _____ pm/pm O three time a week from: _____ am/pm to _____ pm/pm O Four times a week from: _____ am/pm to _____ pm/pm O Daily (five times a week) from: _____ am/pm to _____ pm/pm O More than five times a week from: _____ am/pm to _____ pm/pm
Home address	_____ _____ _____
Home telephone number	_____
Home fax number	_____
Health service payment	O self-payment O Private insurance O Company insurance O Government health coverage (BPJS) O Other: _____

Weight: _____ kg	Height: _____ cm	Temperature: _____ ℃	Blood pressure: _____ mmHg

PARENT'S INFORMATION

FATHER

Father's name	_____
Place and date of birth	_____
Home address	O Same with patient's address O Different address: _____ _____
Home telephone number	O Same with patient's telephone number

	O Different number: _____
Mobile number	_____
Email address	_____ _____
MOTHER	
Mother's name	_____
Place and date of birth	_____
Home address	O Same with patient's address O Different address: _____ _____
Home telephone number	O Same with patient's telephone number O Different number: _____
Mobile number	_____
Email address	_____

Date : |___|___| – |___|___| – 201 |___|

REGISTRATION ID | | | |

Doctor ID : |___|___|___|

Site ID : |___|___|___|

CR01 – ELIGIBILITY FORM

INCLUSION CRITERIA	
O Yes O No	Definite or suspected acute otitis media Were you able to confirm otoscopically? O Yes O No
O Yes O No	Aged 6 months to 12 years
O Yes O No	Available for follow-up visits

EXCLUSION CRITERIA	
O Yes O No	Major medical conditions (e.g. heart failure, renal insufficiency, DM, peptic ulcers)
O Yes O No	Immunocompromised (e.g. cancer treatment, HIV)
O Yes O No	Congenital malformation/syndromes (cleft palate)
O Yes O No	Ventilation tube(s)
O Yes O No	Exposed to persons with varicella/active Zoster infection in the past 3 weeks with no prior history of varicella infection or immunisation
O Yes O No	Has taken oral, injection, or topical steroids in the past 4 weeks
O Yes O No	Has taken antibiotics in the past 2 weeks
O Yes O No	Hypersensitive to prednisolone or other steroids

Is this child eligible for the trial?

All 'YES' at the inclusion criteria, AND
All 'NO' at the exclusion criteria
Eligible, then INCLUDE ○

At least one 'NO' at the inclusion criteria, OR
At least one 'YES' at the exclusion criteria
Not eligible, then EXCLUDE ○

Obtaining the CONSENT

NOT giving CONSENT → **EXCLUDE** ○

Giving CONSENT → **INCLUDE** ○

Do they have these following symptoms?

O Yes O No	Moderate to severe symptoms, locally or systemically (moderate to severe ear pain, fever ⩾39°C, complications)
O Yes O No	Aged younger than 2 years with bilateral acute otitis media
O Yes O No	With perforation of tympanic membrane(s)
O Yes O No	If visible, otoscopic finding shows moderate to severe bulging and/or yellowish purulent tympanic membrane(s)

At least one 'YES' → **SEVERE AOM** ○

All 'NO' → **MILD AOM** ○

For each question, please tick (✓) your answer in the circle

REGISTRATION ID | | | |

CRF02 – BASELINE HISTORY FORM

1 Did (do) you breastfeed your child? O Yes O No

If you do, until the age of O ≤ 2 months O 2 – 6 months O > 6 months O Present

2 Does your child attend a day-care O Yes O No

How many days in a week? O ≤ 2 days O > 2 days

3 Have your child had an influenzae vaccine? O Yes O No

If yes, year : _____

4 Have your child had a pneumococcus vaccine (PCV)? O Yes O No

If yes, year : _____

5 How many episodes of recurrent acute respiratory infection (runny nose, cough, sore throat, fever) in the past year?

O ≤ 3 episodes O > 3 episodes to 6 episodes O > 6 episodes

6 Did your child have a history of 3 or more episodes of ear infection (ear pain, ear discharge, diarrhoea, or vomiting) during the past 12 months? O Yes O No

7 At what age did the first episode of ear infection start?

O ≤ 6 months O > 6 to 12 months O >12 to 24 months O 2 to 5 years O > 5 years

8 Does your child have an allergy? (e.g. house dust, cat/dog fur, milk, etc.)

O Yes, allergy to: _____

O No

9 Number of children (including the patient) who live in the house _____ children

10 Number of persons who smoke at home _____ person(s)

REGISTRATION ID | | | |

CRF 03 – OUTCOMES FORM

Visit 0 (Baseline) : |___|___| – |___|___| – 20 |___|___|

Outcome: Symptoms (for physician)

1	**Does your child experience discharge from the ear(s)?**	O Yes	O No
2	**Does your child experience intense ear pain and pain behind the ear?**	O Yes	O No
3	**Does your child experience swelling/bulging, redness, tenderness, or dropping behind or of the ear(s)?**	O Yes	O No
4	**Does your child experience facial asymmetry (e.g. when the child smiles, cries)?**	O Yes	O No

Outcome: Physical examination (for physician)

5.1 **Weight** _____ kg | 5.2 **Height** _____ cm | 5.3 **Temp.** _____ °C | 5.4 **BP** _____ / _____ mmHg

6	**Nose**	O Normal	O Oedema	O Hyperaemic	O Livid	O Serous discharge	O Mucoid discharge
7	**Tonsils**	O Normal	O Hyperaemic	O Detritus	O Tonsil(s) T1	O Tonsil(s) T2	O Tonsil(s) T3-4
8	**Pharynx**	O Normal	O Hyperaemic	O Oedema	O Granules	O Post nasal drip (PND)	

9 Otoscopic findings

O Normal O Erythema O Air fluid level O Complete effusion O Opacification O Mild bulging
O Moderate to severe bulging (bulging rounded appearance) O Bulla O Perforation

10 Medicines that have been taken before the baseline visit (please circle your dose measurement)

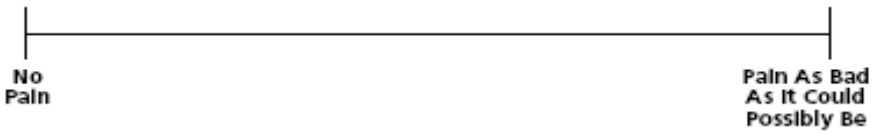
1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day

11 Medicines prescribed by physician (you) at the baseline visit

Antibiotic	Dose : _____mg / body weight kg	Frequency : _____ / day for _____ days
Other medicine		
1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day

Outcome: Symptoms (for patients and the parents. Physician will help them to complete these in the symptom diary)

12 Please place a vertical line across the available horizontal line that best describes your or your child's pain during the past 24 hours?



For each question, please tick (✓) your answer on the circles or write you answer on _____

13 We are interest finding out how your child has been doing. For each question, please place a check mark in the circle corresponding to your child's symptoms. Please answer all questions			
13.1 Over the past 12 h, has your child been tugging, rubbing, or holding the ear(s) more than usual?	O No	O A little	O A lot
13.2 Over the past 12 h, has your child been crying more than usual?	O No	O A little	O A lot
13.3 Over the past 12 h, has your child been more irritable or fussy than usual?	O No	O A little	O A lot
13.4 Over the past 12 h, has your child been having more difficulty sleeping than usual?	O No	O A little	O A lot
13.5 Over the past 12 h, has your child been less playful or active than usual?	O No	O A little	O A lot
13.6 Over the past 12 h, has your child been eating less than usual?	O No	O A little	O A lot
13.7 Over the past 12 h, has your child been having fever or feeling warm to touch?	O No	O A little	O A lot

14 Tympanometry findings (for audiologist) ***R: Right; L: Left***

Tympanogram types (will be completed by physician) [R] Type _____ / [L] Type _____

Ear canal vol (ECV) [R] _____ mL/ [L] _____ mL Static acoustic admittance [R] _____ mL/ [L] _____ mL

Compliance (SC) [R] _____ mL/ [L] _____ mL Middle Ear Pressure or TPP [R] _____ daPa/ [L] _____ daPa

Gradient or TW [R] _____ daPa/ [L] _____ daPa

Put the copy of tympanometry copies here

Follow-up Visit-01 (Day-3) : |___|___|–|___|___|– 20 |___|___|

Outcome: Symptoms (for physician)

1	**Does your child experience discharge from the ear(s)?**	O Yes	O No
2	**Does your child experience intense ear pain and pain behind the ear?**	O Yes	O No
3	**Does your child experience swelling/bulging, redness, tenderness, or dropping behind or of the ear(s)?**	O Yes	O No
4	**Does your child experience facial asymmetry (e.g. when the child smiles, cries)?**	O Yes	O No

Outcome: Physical examination (for physician)

5.1 **Weight** _____ kg | 5.2 **Height** _____ cm | 5.3 **Temp.** _____ °C | 5.4 **BP** _____ / _____ mmHg

6	**Nose**	O Normal	O Oedema	O Hyperaemic	O Livid	O Serous discharge	O Mucoid discharge
7	**Tonsils**	O Normal	O Hyperaemic	O Detritus	O Tonsil(s) T1	O Tonsil(s) T2	O Tonsil(s) T3-4
8	**Pharynx**	O Normal	O Hyperaemic	O Oedema	O Granules	O Post nasal drip (PND)	

9 Otoscopic findings

O Normal O Erythema O Air fluid level O Complete effusion O Opacification O Mild bulging
O Moderate to severe bulging (bulging rounded appearance) O Bulla O Perforation

10 Medicines prescribed by physician (you) (please circle your dose measurement)

Antibiotic	Dose : _____mg / body weight kg Frequency : _____ / day for _____ days

Other medicine

1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day

11 Medicines not prescribed by physician (you) you or seek from other places (e.g. other physician, OTC)

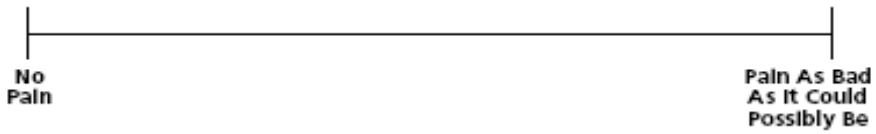
Antibiotic	Dose : _____mg / body weight kg Frequency : _____ / day for _____ days

Other medicine

1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day

Outcome: Symptoms *** For patients ***

12 Please place a vertical line across the available horizontal line that best describes your or your child's pain during the past 24 hours?



13 We are interest finding out how your child has been doing. For each question, please place a check mark in the circle corresponding to your child's symptoms. Please answer all questions

13.1 Over the past 12 h, has your child been tugging, rubbing, or holding the ear(s) more than usual?	O No	O A little	O A lot
13.2 Over the past 12 h, has your child been crying more than usual?	O No	O A little	O A lot
13.3 Over the past 12 h, has your child been more irritable or fussy than usual?	O No	O A little	O A lot
13.4 Over the past 12 h, has your child been having more difficulty sleeping than usual?	O No	O A little	O A lot
13.5 Over the past 12 h, has your child been less playful or active than usual?	O No	O A little	O A lot
13.6 Over the past 12 h, has your child been eating less than usual?	O No	O A little	O A lot
13.7 Over the past 12 h, has your child been having fever or feeling warm to touch?	O No	O A little	O A lot

14 Side effects

Does your child have these complaints after taking the medicine

14.1 Increased appetite	O Yes	O No	14.8 Drowsiness	O Yes	O No
14.2 Increased urine amount	O Yes	O No	14.9 Anxiety/distractibility/mood swing	O Yes	O No
14.3 Weight gain	O Yes	O No	14.10 Headache	O Yes	O No
14.4 Gastritis/abdominal pain	O Yes	O No	14.11 Skin rash or diaper rash	O Yes	O No
14.5 Nausea	O Yes	O No	14.12 Candidiasis	O Yes	O No
14.6 Vomiting	O Yes	O No	14.13 Dry mouth / throat irritation	O Yes	O No
14.7 Diarrhea	O Yes	O No	14.14 Sleep disturbance	O Yes	O No

Others: _____

Did you bring your child to doctor (clinic or outpatient)? O Yes O No
Reason: _____
Medicine prescribed: _____

Has your child has been admitted to hospital? O Yes O No
Reason: _____
Medicine prescribed: _____

Regarding the side effects, your action is/are (you may answer more than one):

O Discontinuation of the trial drug (prednisolone)

O Continuation of the trial drug

O Discontinuation of other concomitant drugs as follows:

1. _____ 3. _____
2. _____ 4. _____

The treatment you prescribed for the management of side effects

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

Does this child require specific or additional tests or examination?

O No

O Yes. Please specify with the results:

1. _____
2. _____
3. _____

Does this child require specific or additional treatment/medicine

O No

O Yes. Please specify the treatment:

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

Does this child require a hospitalisation?

O No

O Yes. Please explain your reasons to hospitalise this child and the treatment will be given

Reason: _____

_____

The treatment:

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

15 Tympanometry findings

Tympanogram types (will be completed by physician) [R] Type _____ / [L] Type _____

Ear canal vol (ECV) [R] _____ mL/ [L] _____ mL Static acoustic admittance [R] _____ mL/ [L] _____ mL

Compliance (SC) [R] _____ mL/ [L] _____ mL Middle Ear Pressure or TPP [R] _____ daPa/ [L] _____ daPa

Gradient or TW [R] _____ daPa/ [L] _____ daPa

Put the copy of tympanometry copies here

Follow-up Visit 02 (Day-7) : |___|___|–|___|___|– 20|___|___|

Outcome: Symptoms *** For physicians only ***

1	**Does your child experience discharge from the ear(s)?**	O Yes	O No
2	**Does your child experience intense ear pain and pain behind the ear?**	O Yes	O No
3	**Does your child experience swelling/bulging, redness, tenderness, or dropping behind or of the ear(s)?**	O Yes	O No
4	**Does your child experience facial asymmetry (e.g. when the child smiles, cries)?**	O Yes	O No

Outcome: Physical examination *** For physicians only ***

5.1 **Weight** _____ kg | 5.2 **Height** _____ cm | 5.3 **Temp.** _____ °C | 5.4 **BP** _____ / _____ mmHg

6	**Nose**	O Normal	O Oedema	O Hyperaemic	O Livid	O Serous discharge	O Mucoid discharge
7	**Tonsils**	O Normal	O Hyperaemic	O Detritus	O Tonsil(s) T1	O Tonsil(s) T2	O Tonsil(s) T3-4
8	**Pharynx**	O Normal	O Hyperaemic	O Oedema	O Granules	O Post nasal drip (PND)	

9 Otoscopic findings

O Normal O Erythema O Air fluid level O Complete effusion O Opacification O Mild bulging
O Moderate to severe bulging (bulging rounded appearance) O Bulla O Perforation

10 Medicines prescribed by physician (you)

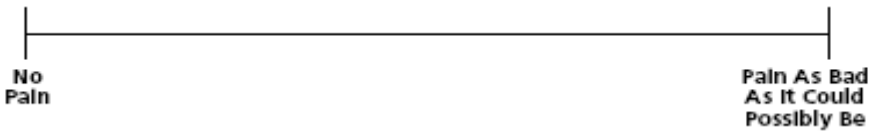
Antibiotic	Dose : _____mg / body weight kg Frequency : _____ / day for _____ days
Other medicine	
1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day

11 Medicines not prescribed by physician (you) you or seek from other places (e.g. other physician, OTC)

Antibiotic	Dose : _____mg / body weight kg Frequency : _____ / day for _____ days
Other medicine	
1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon Frequency : _____ / day

Outcome: Symptoms *** For patients ***

12 Please place a vertical line across the available horizontal line that best describes your or your child's pain during the past 24 hours?



For each question, please tick (✓) your answer on the circles or write you answer on _____

13 We are interest finding out how your child has been doing. For each question, please place a check mark in the circle corresponding to your child's symptoms. Please answer all questions

13.1 Over the past 12 h, has your child been tugging, rubbing, or holding the ear(s) more than usual?	O No	O A little	O A lot
13.2 Over the past 12 h, has your child been crying more than usual?	O No	O A little	O A lot
13.3 Over the past 12 h, has your child been more irritable or fussy than usual?	O No	O A little	O A lot
13.4 Over the past 12 h, has your child been having more difficulty sleeping than usual?	O No	O A little	O A lot
13.5 Over the past 12 h, has your child been less playful or active than usual?	O No	O A little	O A lot
13.6 Over the past 12 h, has your child been eating less than usual?	O No	O A little	O A lot
13.7 Over the past 12 h, has your child been having fever or feeling warm to touch?	O No	O A little	O A lot

14 Side effects

Does your child have these complaints after taking the medicine

14.1 Increased appetite	O Yes	O No	14.8 Drowsiness	O Yes	O No
14.2 Increased urine amount	O Yes	O No	14.9 Anxiety/distractibility/mood swing	O Yes	O No
14.3 Weight gain	O Yes	O No	14.10 Headache	O Yes	O No
14.4 Gastritis/abdominal pain	O Yes	O No	14.11 Skin rash or diaper rash	O Yes	O No
14.5 Nausea	O Yes	O No	14.12 Candidiasis	O Yes	O No
14.6 Vomiting	O Yes	O No	14.13 Dry mouth / throat irritation	O Yes	O No
14.7 Diarrhea	O Yes	O No	14.14 Sleep disturbance	O Yes	O No

Others: _____

Did you bring your child to doctor (clinic or outpatient)? O Yes O No
Reason: _____
Medicine prescribed: _____

Has your child has been admitted to hospital? O Yes O No
Reason: _____
Medicine prescribed: _____

Regarding the side effects, your action is/are (you may answer more than one):

O Discontinuation of the trial drug (prednisolone)

O Continuation of the trial drug

O Discontinuation of other concomitant drugs as follows:

1. _____ 3. _____
2. _____ 4. _____

The treatment you prescribed for the management of side effects

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

Does this child require specific or additional tests or examination?

O No

O Yes. Please specify with the results:

1. _____
2. _____
3. _____

Does this child require specific or additional treatment/medicine

O No

O Yes. Please specify the treatment:

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

Does this child require a hospitalisation?

O No

O Yes. Please explain your reasons to hospitalise this child and the treatment will be given

Reason: _____

_____

The treatment:

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

15 Tympanometry findings

Tympanogram types (will be completed by physician) [R] Type _____ / [L] Type _____

Ear canal vol (ECV) [R] _____ mL/ [L] _____ mL Static acoustic admittance [R] _____ mL/ [L] _____ mL

Compliance (SC) [R] _____ mL/ [L] _____ mL Middle Ear Pressure or TPP [R] _____ daPa/ [L] _____ daPa

Gradient or TW [R] _____ daPa/ [L] _____ daPa

Put the copy of tympanometry copies here

Follow-up Visit 03 (Day-30) : |___|___| – |___|___| – 20 |___|___|

Outcome: Symptoms – Patient

1	Within the past one month, does your child experience a new episode of ear pain with fever or runny nose, cough, or sore throat?	O Yes O No When? _____ days / weeks ago How long? _____ days / weeks (please circle and write your answers)

Outcome: Physical examination

2.1	**Weight**	_____ kg	2.2 **Height**	_____ cm	2.3 **Temp.**	_____ °C	2.4 **BP** _____ / _____ mmHg
3	**Nose**	O Normal	O Oedema	O Hyperaemic	O Livid	O Serous discharge	O Mucoid discharge
4	**Tonsils**	O Normal	O Hyperaemic	O Detritus	O Tonsil(s) T1	O Tonsil(s) T2	O Tonsil(s) T3-4
5	**Pharynx**	O Normal	O Hyperaemic	O Oedema	O Granules	O Post nasal drip (PND)	

6 Otoscopic findings

O Normal O Erythema O Air fluid level O Complete effusion O Opacification O Mild bulging

O Moderate to severe bulging (bulging rounded appearance) O Bulla O Perforation

7 Tympanometry findings

Tympanogram types (will be completed by physician) [R] Type _____ / [L] Type _____

Ear canal vol. [R] _____ mL/ [L] _____ mL Static acoustic admittance [R] _____ mL/ [L] _____ mL

Compliance [R] _____ mL/ [L] _____ mL Middle Ear Pressure or TPP [R] _____ daPa/ [L] _____ daPa

Gradient or TW [R] _____ daPa/ [L] _____ daPa

Put the copy of tympanometry copies here

Follow-up Visit 04 (Day-90) : |___|___| – |___|___| – 20 |___|___|

Outcome: Symptoms – Patient

1	Within the past one month, does your child experience a new episode of ear pain with fever or runny nose, cough, or sore throat?	O Yes O No When? _____ days / weeks ago How long? _____ days / weeks (please write and circle your answer)

Outcome: Physical examination

2.1	**Weight** _____ kg	2.2 **Height** _____ cm	2.3 **Temp.** _____ °C	2.4 **BP** _____ / _____ mmHg		
3	**Nose**	O Normal	O Oedema	O Hyperaemic	O Livid	O Serous discharge	O Mucoid discharge
4	**Tonsils**	O Normal	O Hyperaemic	O Detritus	O Tonsil(s) T1	O Tonsil(s) T2	O Tonsil(s) T3-4
5	**Pharynx**	O Normal	O Hyperaemic	O Oedema	O Granules	O Post nasal drip (PND)	

6 Otoscopic findings

O Normal O Erythema O Air fluid level O Complete effusion O Opacification O Mild bulging

O Moderate to severe bulging (bulging rounded appearance) O Bulla O Perforation

7 Tympanometry findings

Tympanogram types (will be completed by physician) [R] Type _____ / [L] Type _____

Ear canal vol (ECV) [R] _____ mL/ [L] _____ mL Static acoustic admittance [R] _____ mL/ [L] _____ mL

Compliance (SC) [R] _____ mL/ [L] _____ mL Middle Ear Pressure or TPP [R] _____ daPa/ [L] _____ daPa

Gradient or TW [R] _____ daPa/ [L] _____ daPa

Put the copy of tympanometry copies here

***** End *****

Additional visit : |___|___|–|___|___|– 20|___|___|

Outcome: Symptoms (for physician only)

1	**Does your child experience discharge from the ear(s)?**	O Yes	O No
2	**Does your child experience intense ear pain and pain behind the ear?**	O Yes	O No
3	**Does your child experience swelling/bulging, redness, tenderness, or dropping behind or of the ear(s)?**	O Yes	O No
4	**Does your child experience facial asymmetry (e.g. when the child smiles, cries)?**	O Yes	O No

Outcome: Physical examination (for physician only)

5.1 **Weight** _____ kg | 5.2 **Height** _____ cm | 5.3 **Temp.** _____ °C | 5.4 **BP** _____ / _____ mmHg

6	**Nose**	O Normal	O Oedema	O Hyperaemic	O Livid	O Serous discharge	O Mucoid discharge
7	**Tonsils**	O Normal	O Hyperaemic	O Detritus	O Tonsil(s) T1	O Tonsil(s) T2	O Tonsil(s) T3-4
8	**Pharynx**	O Normal	O Hyperaemic	O Oedema	O Granules	O Post nasal drip (PND)	

9 Otoscopic findings

O Normal O Erythema O Air fluid level O Complete effusion O Opacification O Mild bulging
O Moderate to severe bulging (bulging rounded appearance) O Bulla O Perforation

10 Medicines prescribed by physician (you)

Antibiotic	Dose : _____mg / body weight kg Frequency : _____ / day for _____ days

Other medicine

1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day

11 Medicines not prescribed by physician (you) you or seek from other places (e.g. other physician, OTC)

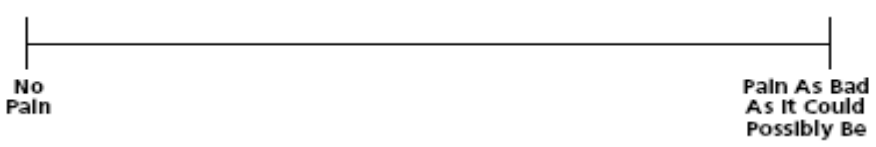
Antibiotic	Dose : _____mg / body weight kg Frequency : _____ / day for _____ days

Other medicine

1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day

Outcome: Symptoms *** For patients ***

14 Please place a vertical line across the available horizontal line that best describes your or your child's pain during the past 24 hours?



15 We are interest finding out how your child has been doing. For each question, please place a check mark in the circle corresponding to your child's symptoms. Please answer all questions

13.1 Over the past 12 h, has your child been tugging, rubbing, or holding the ear(s) more than usual?	O No	O A little	O A lot
13.2 Over the past 12 h, has your child been crying more than usual?	O No	O A little	O A lot
13.3 Over the past 12 h, has your child been more irritable or fussy than usual?	O No	O A little	O A lot
13.4 Over the past 12 h, has your child been having more difficulty sleeping than usual?	O No	O A little	O A lot
13.5 Over the past 12 h, has your child been less playful or active than usual?	O No	O A little	O A lot
13.6 Over the past 12 h, has your child been eating less than usual?	O No	O A little	O A lot
13.7 Over the past 12 h, has your child been having fever or feeling warm to touch?	O No	O A little	O A lot

14 Side effects

Does your child have these complaints after taking the medicine

14.1 Increased appetite	O Yes	O No	14.8 Drowsiness	O Yes	O No
14.2 Increased urine amount	O Yes	O No	14.9 Anxiety/distractibility/mood swing	O Yes	O No
14.3 Weight gain	O Yes	O No	14.10 Headache	O Yes	O No
14.4 Gastritis/abdominal pain	O Yes	O No	14.11 Skin rash or diaper rash	O Yes	O No
14.5 Nausea	O Yes	O No	14.12 Candidiasis	O Yes	O No
14.6 Vomiting	O Yes	O No	14.13 Dry mouth / throat irritation	O Yes	O No
14.7 Diarrhea	O Yes	O No	14.14 Sleep disturbance	O Yes	O No

Others: _____

Did you bring your child to doctor (clinic or outpatient)? O Yes O No
Reason: _____
Medicine prescribed: _____

Has your child has been admitted to hospital? O Yes O No
Reason: _____
Medicine prescribed: _____

Regarding the side effects, your action is/are (you may answer more than one):

O Discontinuation of the trial drug (prednisolone)

O Continuation of the trial drug

O Discontinuation of other concomitant drugs as follows:

1. _____ 3. _____
2. _____ 4. _____

The treatment you prescribed for the management of side effects

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

Does this child require specific or additional tests or examination?

O No

O Yes. Please specify with the results:

1. _____
2. _____
3. _____

Does this child require specific or additional treatment/medicine

O No

O Yes. Please specify the treatment:

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

Does this child require a hospitalisation?

O No

O Yes. Please explain your reasons to hospitalise this child and the treatment will be given

Reason: _____

_____

The treatment:

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

15 Tympanometry findings

Tympanogram types (will be completed by physician) [R] Type _____ / [L] Type _____

Ear canal vol (ECV) [R] _____ mL/ [L] _____ mL Static acoustic admittance [R] _____ mL/ [L] _____ mL

Compliance (SC) [R] _____ mL/ [L] _____ mL Middle Ear Pressure or TPP [R] _____ daPa/ [L] _____ daPa

Gradient or TW [R] _____ daPa/ [L] _____ daPa

Put the copy of tympanometry copies here

Additional visit : |___|___|–|___|___|– 20|___|___|

Outcome: Symptoms (for physician only)

1	**Does your child experience discharge from the ear(s)?**	O Yes	O No
2	**Does your child experience intense ear pain and pain behind the ear?**	O Yes	O No
3	**Does your child experience swelling/bulging, redness, tenderness, or dropping behind or of the ear(s)?**	O Yes	O No
4	**Does your child experience facial asymmetry (e.g. when the child smiles, cries)?**	O Yes	O No

Outcome: Physical examination (for physician only)

5.1 **Weight** _____ kg | 5.2 **Height** _____ cm | 5.3 **Temp.** _____ °C | 5.4 **BP** _____ / _____ mmHg

6	**Nose**	O Normal	O Oedema	O Hyperaemic	O Livid	O Serous discharge	O Mucoid discharge
7	**Tonsils**	O Normal	O Hyperaemic	O Detritus	O Tonsil(s) T1	O Tonsil(s) T2	O Tonsil(s) T3-4
8	**Pharynx**	O Normal	O Hyperaemic	O Oedema	O Granules	O Post nasal drip (PND)	

9 Otoscopic findings

O Normal O Erythema O Air fluid level O Complete effusion O Opacification O Mild bulging
O Moderate to severe bulging (bulging rounded appearance) O Bulla O Perforation

10 Medicines prescribed by physician (you)

Antibiotic	Dose : _____mg / body weight kg Frequency : _____ / day for _____ days

Other medicine

1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day

11 Medicines not prescribed by physician (you) you or seek from other places (e.g. other physician, OTC)

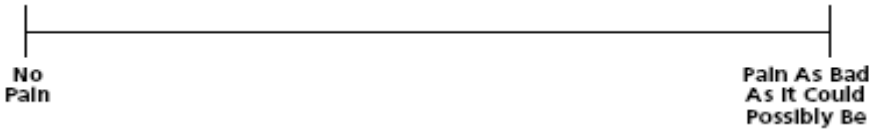
Antibiotic	Dose : _____mg / body weight kg Frequency : _____ / day for _____ days

Other medicine

1. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
2. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
3. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
4. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day
5. _____	Dose : _____mg per BW kg / Teaspoon / Tablespoon	Frequency : _____ / day

Outcome: Symptoms *** For patients ***

12 Please place a vertical line across the available horizontal line that best describes your or your child's pain during the past 24 hours?



13 We are interest finding out how your child has been doing. For each question, please place a check mark in the circle corresponding to your child's symptoms. Please answer all questions			
13.1 Over the past 12 h, has your child been tugging, rubbing, or holding the ear(s) more than usual?	O No	O A little	O A lot
13.2 Over the past 12 h, has your child been crying more than usual?	O No	O A little	O A lot
13.3 Over the past 12 h, has your child been more irritable or fussy than usual?	O No	O A little	O A lot
13.4 Over the past 12 h, has your child been having more difficulty sleeping than usual?	O No	O A little	O A lot
13.5 Over the past 12 h, has your child been less playful or active than usual?	O No	O A little	O A lot
13.6 Over the past 12 h, has your child been eating less than usual?	O No	O A little	O A lot
13.7 Over the past 12 h, has your child been having fever or feeling warm to touch?	O No	O A little	O A lot

14 Side effects

Does your child have these complaints after taking the medicine

14.1 Increased appetite	O Yes	O No	14.8 Drowsiness	O Yes	O No
14.2 Increased urine amount	O Yes	O No	14.9 Anxiety/distractibility/mood swing	O Yes	O No
14.3 Weight gain	O Yes	O No	14.10 Headache	O Yes	O No
14.4 Gastritis/abdominal pain	O Yes	O No	14.11 Skin rash or diaper rash	O Yes	O No
14.5 Nausea	O Yes	O No	14.12 Candidiasis	O Yes	O No
14.6 Vomiting	O Yes	O No	14.13 Dry mouth / throat irritation	O Yes	O No
14.7 Diarrhea	O Yes	O No	14.14 Sleep disturbance	O Yes	O No

Others: _____

Did you bring your child to doctor (clinic or outpatient)? O Yes O No
Reason: _____
Medicine prescribed: _____

Has your child has been admitted to hospital? O Yes O No
Reason: _____
Medicine prescribed: _____

Regarding the side effects, your action is/are (you may answer more than one):

O Discontinuation of the trial drug (prednisolone)
O Continuation of the trial drug
O Discontinuation of other concomitant drugs as follows:

1. _____ 3. _____
2. _____ 4. _____

The treatment you prescribed for the management of side effects

1. _____; Dose _____; Frequency _____ / day
2. _____; Dose _____; Frequency _____ / day
3. _____; Dose _____; Frequency _____ / day
4. _____; Dose _____; Frequency _____ / day

Does this child require specific or additional tests or examination?

O No
O Yes. Please specify with the results:

1. _____
2. _____
3. _____

Does this child require specific or additional treatment/medicine

O No

	O Yes. Please specify the treatment: 1. _____; Dose _____; Frequency _____ / day 2. _____; Dose _____; Frequency _____ / day 3. _____; Dose _____; Frequency _____ / day 4. _____; Dose _____; Frequency _____ / day
Does this child require a hospitalisation?	O No O Yes. Please explain your reasons to hospitalise this child and the treatment will be given Reason: _____ _____ The treatment: 1. _____; Dose _____; Frequency _____ / day 2. _____; Dose _____; Frequency _____ / day 3. _____; Dose _____; Frequency _____ / day 4. _____; Dose _____; Frequency _____ / day

15 Tympanometry findings

Tympanogram types (will be completed by physician) [R] Type _____ / [L] Type _____

Ear canal vol (ECV) [R] _____ mL/ [L] _____ mL Static acoustic admittance [R] _____ mL/ [L] _____ mL

Compliance (SC) [R] _____ mL/ [L] _____ mL Middle Ear Pressure or TPP [R] _____ daPa/ [L] _____ daPa

Gradient or TW [R] _____ daPa/ [L] _____ daPa

Put the copy of tympanometry copies here

REGISTRATION ID | | | |

Nurse ID : |___|___|___| Site ID : |___|___|___| Date : |___|___| – |___|___| – 201 |___|

CR04 – RANDOMISATION FORM

The severity of acute otitis media	O Mild acute otitis media O Severe acute otitis media
Patient's date of birth	dd|___|___| – mm|___|___| – yyyy|___|___|___|___|
Age in month or year	|___|___| month(s) OR |___|___| year(s)
Dosage of prednisolone (Tick the circle responding correct dose for this child)	O 10 mg per day (aged 6 months to < 2 years) O 20 mg per day (aged 2 years to < 6 years) O 30 mg per day (aged 6 years to 12 years)

RANDOMISATION

Access to the randomisation website by clicking this link:

http://www.

Or

Call Dr Respati at +62 8111 012 185

Randomisation ID	|___|___|___|
Allocation of the intervention	O Prednisolone O Control (no prednisolone)

Nurse 's signature
Nurse's full name
Date

REGISTRATION ID ☐☐☐

SERIOUS ADVERSE EVENTS REPORTING FORM

SUBJECT INFORMATION

Weight (kg)	|____|____| , |____|____| kg
List any relevant tests, laboratory data, history, including pre-existing medical conditions	_____
Any concomitant medication	_____

ADVERSE EVENT

Report type	☐ Initial report	☐ Follow-up	☐ Final
Reason for reporting	☐ Requires or prolongs hospitalization	☐ Congenital anomaly	
	☐ Permanently disabling or incapacitating	☐ Life threatening	
	☐ Overdose	☐ Death	
	☐ Other (please specify) _____	Date of death _____	
		Cause of death _____	

SUSPECTED DRUG

Name of suspected drug	_____	Generic name	_____
Dose details	_____	Name of manufacturer	_____
Date of occurrence	|____|____| - |____|____| - |____|____|____|____| *(date – month – year)*		
Duration of event	|____|____| month(s) |____|____| day(s)		
Starting date of medication	|____|____| - |____|____| - |____|____|____|____| *(date – month – year)*		
Route of administration	_____	Indication	_____
Discontinuation of drug because of event	☐ No	☐ Yes	Dated (date / month / year) : _____
If stopped/lowered dose, did the event resolve after this?	☐ Yes	☐ No	☐ N/A
If reintroduced did the event reappear?	☐ Yes	☐ No	☐ N/A
Outcomes	☐ Recovered	☐ Recovered with sequelae	☐ Continuing
	☐ Change in SAE	☐ Patient died	☐ Unknown
Severity	☐ Mild	☐ Moderate	☐ Severe
Action taken with study drug	☐ None	☐ Dose reduced	☐ Discontinued
	☐ Dose temporarily reduced	☐ Discontinued temporarily	
Other action*	☐ None	☐ Treated with medication	☐ Other

Withdrawn from the trial due to SAE	☐ No ☐ Yes
REPORTER INFORMATION	
Signature of reporter	_____
Date of signing	|____|____| - |____|____| - |____|____|____|____| *(date – month – year)*
Full name	_____

REGISTRATION ID | | | |

FEEDBACK FORM (for physician only)

Questions		Please place a tick (√) in O the box corresponding to your answer				
Participation Information Sheet and Consent Form	How do you rate the process of providing **patient information and informed consent** to your patient?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please place a check mark in O corresponding to or write you reason(s). You may choose more than one.	O It was too difficult to explain this to my patient/parent O Time consuming O There was too much information to explain O I was not sure that my patient understood O Other: _____ _____				
Visual Analogue Scale (VAS)	How do you rate the process of providing related information and assisting your patient/parent to complete **the visual analogue scale (VAS)**?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please place a check mark in O corresponding to or write you reason(s). You may choose more than one.	O It was too difficult to explain this to my patient/parent O Time consuming O I was not sure that my patient/parent understood O My patient/parent seem not confidence with the answer O Other: _____ _____				
Acute Otitis Media – Severity of Symptom Scale	How do you rate the process of providing related information and assisting your patient/parent to complete **the acute otitis media – severity of symptom scale (AOM–SOS)**?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult

	If your answer 'difficult' or 'very difficult', please place a check mark in O corresponding to or write you reason(s). You may choose more than one.	O It was too difficult to explain this to my patient/parent O Time consuming O I was not sure that my patient/parent understood O There were several questions that difficult to explain or not suitable for my patient/parent: question no. ___ ; ___ ; ___ ; O Other: _____ _____				
Patient/parent Diary	How do you rate the process of providing related information and assisting your patient/parent to complete **the Patient/parent Diary**?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please place a check mark in O corresponding to or write you reason(s). You may choose more than one.	O It was too difficult to explain this to my patient/parent O Time consuming O I was not sure that my patient/parent understood O The sequence of the questions was too confusing O Too many questions O Other: _____ _____				
Case Report Forms (CRFs)	How do you rate the process in completing the **case report forms (CRFs)**?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please place a check mark in O corresponding to or write you reason(s). You may choose more than one.	O Time consuming O Too much unnecessary information was required O The sequence of the questions was too confusing O Several questions in the CRF were difficult to understand O Other: _____ _____				
Screening and Stratification Process	How do you rate **the recruitment process**, particularly in classifying the children based on their eligibility and stratification criteria?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please	O The form was too complicated O The form was not helping me to screen and stratify my				

	place a check mark in O corresponding to or write you reason(s). You may choose more than one.	patient/ parent O Despite I was guided by the form, I was still found the process was still confusing, particularly in terms of deciding which group my patient/parent should go to (i.e. mild vs severe acute otitis media) O Other: _____ _____

REGISTRATION ID | | | |

FEEDBACK FORM (for audiologist/trained nurse only)

Questions		Please place a tick (√) in O the box corresponding to your answer				
Case Report Forms (CRFs)	How do you rate the process of completing the **tympanometry section** in CRF?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please place a check mark in O corresponding to or write you reason(s). You may choose more than one.	O It was difficult to find the section in the 'outcome form' O The space was too small. I need more space to write-up the results O I was not sure of the interpretation of tympanogram curve types O There were some components that were not provided in the form O Other: _____ _____				

REGISTRATION ID | | | |

FEEDBACK FORM (for nurse only)

	Questions	Please place a tick (√) in O the box corresponding to your answer				
Randomisation	How do you rate **the randomisation process**, in terms of obtaining the study ID and the allocation of the intervention (prednisolone group or control group)	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please place a check mark in the box corresponding to or write you reason(s). You may choose more than one.	O The form was too complicated O It was difficult to access the randomisation centre (randomisation website or by phone) to obtain the study ID and the allocation of the intervention O Other: _____ _____				
Storing Process of Drug Trial	How do you rate the **storing process of the trial drug** in your clinic or hospital and completing the related-form?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please place a check mark in the box corresponding to or write you reason(s). You may choose more than one.	O The 'dispensing and returning form' was too complicated O The procedure was time consuming O The storing required too much work and space O Other: _____ _____				
Preparation Process of Trial Drug	How do you rate the **preparation process of trial drug** according to the patient intervention allocation?	O Very easy	O Easy	O Neutral / moderate	O Difficult	O Very difficult
	If your answer 'difficult' or 'very difficult', please place a check mark in the box corresponding to or write you reason(s). You may choose more than one.	O It was difficult to dispense the medicine. Please write your reason: _____ O It was difficult to give information regarding the use of the trial drug to the patient/parent O It was difficult to ask patient/parent to keep the confidentiality of which group the patient in O Other: _____ _____				

REGISTRATION ID | | | |

FEEDBACK FORM (for parents only)

Question	Please place a tick (√) in O the box corresponding to your answer				
How do you rate the process in completing the scale above **(the visual analogue scale or VAS)**?	O Very easy	O Easy	O Neutral/ moderate	O Difficult	O Very difficult
If your answer 'difficult' or 'very difficult', please place a check mark in the box corresponding to or write you reason(s). You may choose more than one.	O I did not understand how to complete the scale O I need more information from my doctor O The provided information on the form was unclear O My doctor could not provide additional information that I need O Other: _____ _____				
How do you rate the process in completing the scale above **(the acute otitis media – severity of symptom scale or AOM – SOS)**?	O Very easy	O Easy	O Neutral/ moderate	O Difficult	O Very difficult
If your answer 'difficult' or 'very difficult', please place a check mark in the box corresponding to or write you reason(s). You may choose more than one.	O It was difficult to understand the question(s) O The provided answers were confusing O The provided information was unclear O The question(s) was not suitable for my child, therefore I did not know how to answer the question(s) O Other: _____ _____				
How do you rate the process in completing the whole diary?	O Very easy	O Easy	O Neutral/ moderate	O Difficult	O Very difficult
If your answer 'difficult' or 'very difficult', please place a check mark in the box corresponding to or write you reason(s). You may choose more than one.	O I did not understand how to complete this diary O I need more information from my doctor O Time consuming O Too many questions that I do not think it is relevant with my child's condition				

For each question, please tick (✓) your answer in the O or write you answer on ___

	O The sequence of the questions was too confusing O Other: _____ _____

STUDY DRUG DISTRIBUTION FORM

Pharmacist ID : |___|___|___|___| **Site ID** : |___|___|___|

Date received	Number of tablets	Name who received the drug	Signature	Date checked	Number of tablets	Name who checked the drug	Signature	Note

DRUG DISPENSING FORM

Pharmacy ID : |___|___|___|___| **Site ID** : |___|___|___|

Study Registration ID	Date Dispensed	Dose (mg/day)	Number of doses (days)	First or Replacement ('F' or 'R')

DRUG RETURN FORM

Nurse ID : |___|___|___|___| **Site ID** : |___|___|___|

Study Registration ID	Date Returned	Number of left-over drug	Reasons for return

COMPLETED CASE REPORT FORM

Nurse Name / ID :	Protocol : Oral prednisolone for acute otitis media in children: a pilot Pragmatic, randomised, open-label single-blind, controlled study (OPAL study)	Site / Hospital ID :

No	Randomisation ID	Date enrolled to the study	Date of Visit-1 (Day-3)	Date of Visit-2 (Day-7)	Date of Visit-3 (Day-30)	Date of Visit-4 (Day-90)	Date of the completion of the study
			Please tick if patient visited accordingly				

STUDY DRUG DISTRIBUTION FORM

Pharmacist ID : |___|___|___|___| **Site ID** : |___|___|___|

Date received	Number of tablets	Name who received the drug	Signature	Date checked	Number of tablets	Name who checked the drug	Signature	Note

DRUG DISPENSING FORM

Pharmacy ID : |___|___|___|___| **Site ID** : |___|___|___|

Study Registration ID	Date Dispensed	Dose (mg/day)	Number of doses (days)	First or Replacement ('F' or 'R')

DRUG RETURN FORM

Nurse ID : |___|___|___|___| **Site ID** : |___|___|___|

Study Registration ID	Date Returned	Number of left-over drug	Reasons for return

DRUG DISPENSING FORM

Pharmacy ID : |___|___|___|___| **Site ID** : |___|___|___|

Study Registration ID	Date Dispensed	Dose (mg/day)	Number of doses (days)	First or Replacement ('F' or 'R')

Date _____

Prescription for OPAL study medication

Prednisolone doses:

- **Aged 6 months to < 2 years old = 10 mg per day**
- **Aged 2 years to 5 years old = 20 mg per day**
- **Aged six years to 12 years old = 30 mg per day**

Registration ID : _____

Age : _____ **months / year(s)** ***[write and circle your answer]***

Study medication dose : _____ **mg per day =** _____ **tablets per day**

R/ OPAL study medication tab **…….**

Sach lact **add**

m.f. pulveres dtd **No. V**

∫ 1 dd 1 pc (before 9 am)

_____

(sign here)

Follow-up Reminder Card

	Baseline Date	Scheduled Date	Visit Date	Comments
Baseline (Day–0)	_____	_____	_____	_____
Visit–1 (Day–3)		_____	_____	_____
Visit–2 (Day–7)		_____	_____	_____
Visit–3 (Day–30)		_____	_____	_____
Visit–4 (Day–90)		_____	_____	_____

Lupred ® 5

Prednisolone 5 mg

TABLET

COMPOSITION

Each tablet contains:

Prednisolone 5 mg

PHARMACOLOGY

Prednisolone is a systemic corticosteroid with glucocorticoid and anti-inflammatory potencies. The mechanism of action of corticosteroids is thought to be by control of protein synthesis. Corticosteroids react with receptor proteins in the cytoplasm of sensitive cells in many tissues to form a steroid-receptor complex.

INDICATION

Allergic reaction, inflammation and other diseases that require glucocorticoid treatment, such as rheumatoid arthritis, collagen diseases, and dermatology disorders.

DOSAGE AND INSTRUCTION

Adults: 1 – 4 tablets per day or according to the doctor's instruction.

The dosage reduces gradually until reach the lowest effective dose.

PRECAUTION

- Avoid the abrupt discontinuation in a long-term use
- Use with caution in paediatric patients who are still in the growing process
- Not recommended for pregnant and breast-feeding women
- Prolonged use of corticosteroids may produce posterior subcapsular cataracts, glaucoma with possible damage to the optic nerves, and may enhance the establishment of secondary ocular infections due to fungi or viruses
- Risk of secondary adrenocortical insufficiency could be reduced by gradual reduction of dosage
- Use with caution in patients with diabetes mellitus because it can increase the gluconeogenesis and reduce the sensitivity to insulin
- Use with caution in patients with hypothyroidism because it can enhance the effect of corticosteroids
- Use with caution in patients with heart failure, infection diseases, chronic renal failure, and elderly

ADVERSE EFFECTS

- Water balance and electrolytes disturbance: Natrium retention, excretion of potassium, hypokalaemic alkalosis, hypertension, and congestive heart failure
- Musculoskeletal: Muscle weakness, steroid-induced myopathy, osteoporosis, vertebral compression fractures and pathologic fractures of long bones
- Gastrointestinal: Peptic ulceration with haemorrhage and perforation, pancreatitis, abdominal distension and ulcerative esophagitis
- Dermatological: Impaired wound healing, thinning of the skin, facial plethora, increased sweating
- Neurological: seizures, intracranial hypertension with papilloedema (cerebral pseudotumour), vertigo, headache

FAHRENHEIT

PT. PRATAPA NIRMALA

- Endocrine: Disorders of menstruation, suppression of growth in children, secondary adrenocorticoid and non-responsive pituitary (particularly in stress, trauma, surgery or illness), metabolic effects, primarily involving the carbohydrates
- Ophthalmological: Posterior subcapsular cataracts, increased intraocular pressure, glaucoma, and exophthalmos
- Metabolic: Nitrogen depletion due to protein catabolism
- Hypersensitivity: anaphylactic reaction

CONTRAINDICATION

- Patients who are known hypersensitivity to prednisone or prednisolone
- Peptic ulceration, active tuberculosis, osteoporosis, neurological disorders, renal and heart disorders
- Systemic fungal infections and ocular herpes simplex

INTERACTION WITH OTHER MEDICINES

- The use of aspirin and corticosteroid is not recommended in patients with non-specific ulcerative colitis
- Rifampicin, phenytoin, phenobarbital can increase the metabolism of corticosteroids
- Vaccination with live vaccine must be avoided

OVERDOSAGE

There is no specific antidot. Treatment is symptomatic with the dosage being reduced or the drug withdrawn.

STORAGE CONDITION

Store below 30°C.

DOCTOR's PRESCRIPTION IS A MUST

Manufactured by:
PT. PRATAPA NIRMALA
Tangerang – Indonesia

Instruction form for Prednisolone use

We cited the information on the leaflet from:
Medicine for children – information for parents and carers: prednisolone for asthma.
http://www.medicinesforchildren.org.uk/prednisolone-asthma

This elaflet has been written for parents and carers about how to use this medication in children. This information may differ from that provided by the pharmaceutical company, because their information is usually aimed at adult patients. Please read this leaflet carefully. anak.ini disiapkan untuk orang tua dan pengasuh. Informasi ini

Name of drug

Lupred tablet contains of prednisolone.

When should I give prednisolone?

Prednisolone is usually given **once** each day, usually in the morning. Give the medicine at about the same time each day so that this becomes part of your child's daily routine, which will help you to remember.

How much should I give?

Your doctor will work out the amount (the dose) that is right for your child. It is important that you follow your doctor's instructions about how much to give.

How should I give it?

The pharmacist will prepare the prednisolone tablets by crushing the tablets, mixing it with the sweetener, and packing them in a daily paper-pack for your child.

You can mix it with a small amount of soft food such as yogurt, honey or jam, or give a glass of milk or juice. Make sure your child swallows it straight away, without chewing.

When should the medicine start working?

Prednisolone usually takes 4–6 hours to have its full effect.

What if my child is sick (vomits)?

If your child is sick less than 30 minutes after having a dose of prednisolone, give them the same dose again.

If your child is sick more than 30 minutes after having a dose of prednisolone, you do not need to give them another dose. Wait until the next normal dose.

If your child is sick again, please contact us.

What if I forget to give it?

You can give your child the missed dose as soon as you remember on the same day. If you remember after they have gone to bed, do not give them the missed dose. Give the next dose in the morning as usual. Never give a double dose of prednisolone

What if I give too much?

It can be dangerous to give too much prednisolone. If you think you may have given your child too much prednisolone, contact us immediately.

Are there any possible side-effects?

We use medicines to make our children better, but sometimes they have other effects that we don't want (side-effects). It is unlikely that your child will have side-effects if they only take prednisolone for a few days. They are more likely to get side-effects if they are on a high dose, have extra doses or take prednisolone for a long time.

Side effects that you must do something about

- If your child has bad stomach pain or repeated vomiting (being sick), contact us straight away. This may be due to an ulcer or inflammation of the pancreas
- If your child develops a rash or severe/unexplained bruising, contact us straight away, as there may be a problem with your child's blood
- If your child has eye pain or changes in their vision, contact us straight away

Other side effects you need to know about

- child may have stomach ache, feel sick or be sick (vomit) or may have indigestion (heartburn). Giving the medicine with some food may help
- Your child may have an increased appetite and may gain weight while taking prednisolone. You can help by making sure your child has plenty of physical activity, and by offering fruit and vegetables and low-calorie food, rather than food that is high in calories (e.g. cakes, biscuits, sweets)
- Your child may have trouble sleeping and nightmares and may feel depressed, or their behaviour may change in other ways. Contact us for advice if you are concerned

Side effects with high doses or long courses

- Prednisolone can slow growth and affect puberty. It can also cause growth of body hair and irregular periods in girls
- Your child may be more at risk of severe infections. They should stay away from anyone with an infection (such as chicken pox, shingles, measles) if they have not had these illnesses or have not been vaccinated for measles
- If your child is unwell and you are worried about an infection, contact us straight away
- Your child's skin may become thinner, and heal more slowly than usual. Acne (spots) may become worse or your child may develop mouth ulcers or thrush (candidiasis). If you are concerned, contact us
- Your child may develop problems with their hip bones or their bones may become weaker (osteoporosis). The muscles around the hips and shoulders may also become weaker. If your child has any difficulty walking or moving around, contact us
- Occasionally, prednisolone causes diabetes. If your child seems more thirsty than normal, needs to pass urine (wee) often, or starts wetting the bed at night, contact us

There may, sometimes, be other side-effects that are not listed. above. If you notice anything unusual and are concerned, please contact us.

Can other medicines be given at the same time?

You can give your child medicines that contain paracetamol or ibuprofen, unless your doctor has told you not to. Check with us or your doctor before giving any other medicines to your child. This includes herbal or complimentary medicines.

Is there anything else I need to know about prednisolone?

For children who have been taking prednisolone in high doses or for longer than 2-3 weeks

- They must not stop taking the medicine suddenly because they may get withdrawal symptoms: they will feel unwell, dizzy and thirsty and may be sick (vomit). If this occurs, you should contact us straight away
- If your doctor decides to stop prednisolone, they will reduce the dose gradually before stopping it completely. Make sure you follow your doctor's instructions
- Make sure that you always have enough medicine.

Where should I keep this medicine?

- Keep the medicine in a cupboard, away from heat and direct sunlight. It does not need to be kept in the fridge
- Make sure that children cannot see or reach it.
- Keep the medicine in the container it came in

WHO TO CONTACT FOR MORE INFORMATION

OPAL STUDY 24-HOUR CALL CENTRE

08111 012 185