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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)
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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.