Patient/participant information sheet and consent form

Protocol name: Fibrin Glue in Skin Grafts for Skin Cancer (FiGSS)
Investigators: Principal investigator Ekta Paw BSc MBBS
Co-investigators Venkat Vangaveti MSc PhD; Mark Zonta BSc MBBS FRACS; Clare Heal MBChB, DRANZCOG, DipGUMed, FRACGP, MPHTM, PhD; Ronny Gunnarsson MD PhD

1 Introduction

You are invited to take part in this research project. This is because you have a skin cancer which requires a skin graft. The research project is to compare different ways to attach skin grafts

This Participant Information Sheet/Consent Form tells you about the research project. It explains the tests and treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:
- Understand what you have read
- Consent to take part in the research project
- Consent to have the tests and treatments that are described
- Consent to the use of your personal and health information as described.

2 What is the purpose of this research?

Skin cancer is incredibly common in North Queensland. Many people need large sections of skin removed to treat their cancer, and skin grafts to close their wounds. Instead of attaching these grafts with stitches or staples, a newer method is to use Fibrin glue, which is made from a protein found in humans which stops bleeding. By sticking to the whole surface of the graft, it is thought that Fibrin glue may improve healing. It may have an important effect in patients w are more likely to have graft failure, such as those with poor circulation, smokers, or the elderly.

Fibrin glue has been approved by the Australian Federal Government for use in attaching skin grafts for a number of years. There is research already on using it for burns, but not in skin cancer.

The results of this research will be used by the study doctor Ekta Paw to obtain a Masters of Philosophy degree.

3 What does participation in this research involve?

Participation in this project does not change your surgery. For some patients not participating in the trial we may also use the glue, as it is already part of usual care.

If there are no reasons you cannot participate in the study, you will be randomised to either: staples and stitches to attach your graft; or to the group which has fibrin glue to attach the graft. Your surgery will proceed as normal and your follow up appointments will be the same as normal (one week and one month). The only difference is that we will ask some questions about your medical history; your post-operative pain; and we will take photographs of your graft. The photographs will not include anything identifiable, and will only be seen by researchers to assess how well your wound has healed.

This research project has been designed to make sure the researchers interpret the results in a fair and appropriate way and avoids study doctors or participants jumping to conclusions. Safety of the research will be monitored by a data safety management committee. There is also a study steering committee who will continually monitor progress and any unexpected events as they occur.

There are no additional costs associated with participating in this research project, nor will you be paid.

4 What do I have to do?

You will have to attend your surgery date as per usual, and your follow up appointments which are the same as if you were not participating in the study. It is important you attend these appointments on time as it will help assess the effectiveness of the glue. You can continue all your regular medications.

5 Other relevant information about the research project

There will be 334 patients participating in this study, of which half will have the glue used, and half will have stitches or staples used. There are two hospitals in Townsville involved.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep.

7 What are the alternatives to participation?

If you don't participate, your surgery will occur as usual, with the usual follow up. It is possible you may still have Fibrin glue used for your skin graft as it is part of the current standard of care.

8 What are the possible benefits of taking part?

We cannot guarantee or promise that you will receive any benefits from this research; however, possible benefits may include better healing of skin graft, less risk of infection, faster surgery and less pain after surgery. By taking part you may have an increase in the observation of your wounds and because of this problems or issues may be picked up faster. Taking part will enable doctors to know if this glue is truly better or not. If the glue is shown to improve outcomes, future patients may have better healing, less pain, less infections and need to attend hospital less often after having skin grafts.

9 What are the possible risks and disadvantages of taking part?

While Fibrin glue has been approved by the Australian Federal Government, there have been a small number of adverse outcomes reported which have been associated with its use. These have mainly related to hypersensitivity reactions to the proteins. It is for this reason that we will not allow people who have a known allergy to bovine protein to participate in this study. However, it is possible you may have an allergy without knowing about it previously.

Allergy reactions can range from itchiness and redness, to difficulty breathing and a drop in blood pressure. While this is a very rare occurrence, if it does occur it will be within a very short time of exposure to the allergen (Fibrin glue), and you will be closely monitored during and after your surgery for any signs of this so it can be treated quickly.

10 What if I withdraw from this research project?

You are welcome to withdraw from this research project at any time if you no longer wish to be a participant. Your surgery and follow up will go ahead as usual, with no change to the timing or quality of your care. Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, your relationship with those treating you or your relationship with Townsville Hospital/Mater Health Services North Queensland.

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to discuss any health risks or special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the research project results. If you do not want them to do this, you must tell them before you join the research project.

11 Could this research project be stopped unexpectedly?

This research project may be stopped unexpectedly for a variety of reasons. These may include reasons such as:

- Unacceptable side effects
- The treatment being shown not to be effective
- The treatment being shown to work and not need further testing

12 What will happen to information about me?

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project will be that can identify you will remain confidential. Data will be kept in a form which does not identify you, but in case we need to re-identify a participant for medical reasons there will be a code. This code will be kept securely in a password protected electronic format which can only be accessed by the researchers involved in this study. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. Data will be kept securely for 15 years following completion of the study as per James Cook University guidelines.

Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be

identified, except with your permission. Data will only be presented as numerical results with no identification of individual participants

13 Complaints and compensation

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment. If you are eligible for Medicare, you can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital.

14 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Townsville Hospital

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

15 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on 4433 1111 or any of the following people: Dr Mark Zonta, Dr Venkat Vangaveti.

Research Contact Person:
Name: Dr Ekta Paw
Position: Principal House Officer, General Surgery
Phone: 4433 1111
Email: ekta.paw@health.qld.gov.au

This project has been reviewed and approved by the Townsville Hospital and Health Service Human Research Ethics Committee. For concerns relating the conduct of this project contact:
HREC Chairperson
Phone: 07 4433 1440
Email: TSV-Ethics-Committee@health.qld.gov.au

PATIENT/PARTICIPANT CONSENT FORM

PROTOCOL NAME: Fibrin Glue in Skin Grafts for Skin Cancer (FiGSS)

INVESTIGATORS: **Principal investigator** Ekta Paw BSc MBBS
Co-investigators Dr Venkat Vangaveti MSc PhD; Mark Zonta BSc MBBS FRACS;
Clare Heal MBChB, DRANZCOG, DipGUMed, FRACGP, MPHTM, PhD; Ronny Gunnarsson MD PhD

1. The nature and purpose of the research project has been explained to me. I understand it and acknowledge that taking part in this study is voluntary.

2. I have been given an Information Sheet which explains the purpose of the study, the possible benefits, and the possible risks.

3. I understand that I may not directly benefit from taking part in the trial.

4. I understand that, while information gained during the study may be published, I will not be identified and my personal results will remain confidential.

5. I understand that I can withdraw from the study at any stage and that it will not affect my medical care, now or in the future.

6. I have had the opportunity to discuss taking part in this investigation with a family member or friend.

NAME OF PARTICIPANT:

SIGNATURE:

DATED:

I certify that I have explained the study to the patient/volunteer and consider that he/she understands what is involved.

NAME OF PRINCIPAL INVESTIGATOR: Dr Ekta Paw

SIGNATURE: