

PARTICIPANT INFORMATION AND consent form (PICF)

Princess Alexandra Hospital, Brisbane

Full Project Title: Topical therapy for skin premalignancies

Lead Investigator: Professor Kiarash Khosrotehrani

1. Introduction

You are invited to take part in this research project because you are attending the Princess Alexandra Hospital for assessment of skin lesions that might be cancer. The bacteria on sun damaged skin are generally different from those on normal healthy skin. This research project will test whether it is possible to change the bacteria that grow on your sun damaged skin to the ones that are found on normal skin. In the long term, this work might lead to a treatment for sun damaged skin, to reduce the risk of skin cancer.

This Participant Information and Consent Form tells you about the research project. It explains the procedures 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 healthcare worker.

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 you take part or not.

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 participate in the research processes that are described; and

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep. A copy of the consent form will be sent for scanning into your electronic medical record to comply with GCP requirements.

2. What is the purpose of this research project?

1. To determine whether we can change the type of skin resident bacteria using topical probiotic ointments
2. To determine if the changes we induce can be maintained over a 6 month period

Skin cancer is a consequence of sunlight induced genetic damage to the cells that make up skin. Generally, sun damaged skin produces lesions known as actinic keratosis, which can then progress to squamous cell carcinoma (skin cancer). Several studies have demonstrated the presence of abnormal bacteria on skin cancers and precancer lesions, and that these abnormal bacteria can secrete toxins that might encourage progression of sun damaged skin to skin cancer. By altering the bacterial population from potentially harmful to beneficial or normal bacteria, this may aid in decreasing the likelihood of progression of sun damaged skin to skin cancer. To test this, we will apply treatment to your sun-damaged arm skin that might be expected to encourage the growth of normal bacteria, and we will take samples (swabs) of your skin bacteria to see if the treatments do what we expect.

You are invited to participate in this research project because you are over 60 years old and you have presented to the clinic for management of sun damaged skin. A total of 80 people will participate in this project

A short summary of the study is that we’ll collect some information from you about you and your skin. We will take swabs from your normal skin and sun damaged skin on your arms, show you how to apply a treatment to the skin at home, and then ask you to come back on 3 occasions so we can take further swabs from your skin.

3. What does participation in this research project involve?

If you agree to participate in this study, your participation will involve 5 outpatient visits to the Hospital over a period of 6 months, and we will also wish to follow your skin condition after the research visit. To test whether we can change the skin bacteria, you’ll be given an ointment that we will ask you to apply to your skin twice daily (once in the morning and one at night) for a period of 2 weeks. In this study, one arm with actinic keratosis will be used for the treatment, whilst the other arm with sections of healthy skin will be used as a control. The control arm may contain a placebo ointment which will not contain any treatment compounds.

***Research visit***

We will take a short medical history from you, especially about your skin, and about any drugs you may be taking. At your first visit, we will take swabs of the actinic keratosis lesion and of normal skin. We will then demonstrate how to apply the topical ointment. This process is painless and your skin is not damaged in any way by the process.

***Follow up visits***

After the initial visit, you will be required to return to the hospital on the day that treatment is finished (2 weeks following the initial visit). There will then be a follow-up visit 1 week, 3 months and 6 months from the study commencement date. During these 5 visits, we will take further swabs from your skin in the same sites as the original swabs.

1. What will happen to my test samples?

To participate in this project we will require a total of 10 swabs to be taken from your skin for research purposes. The swab will then be cultured and the bacteria will be harvested. In the lab, a DNA extraction will be conducted to sequence the bacterial genomes and output the total microbial population from your skin swab. This data will be analysed and the normal skin and the lesion skin will be compared and contrasted to determine if there are any differences in microbial population during and after treatment.

If after giving us samples for this study you subsequently decide to withdraw from the study, you have an option to have your samples destroyed. Please see section 10 of the form about withdrawal.

1. What are the possible benefits?

While no benefit can be guaranteed, it is hypothesised that the ointment should alter the lesion microflora. Generally, potentially cancer promoting bacterial species have been found on sun damaged skin in abundance. The ointments provided may displace, change or eradicate the cancer promoting bacterial species and may create a healthier skin microenvironment.

6. What are the possible risks?

The treatment may make no difference to the bacteria on your skin. It may cause some local irritation on the skin, in which case we’ll ask you to stop using it.

**7. Other Treatments Whilst on Study**

It is important to tell your doctor and the research staff about any treatments or medications you may be taking, including non-prescription medications, vitamins or herbal remedies and any changes to these during your participation in the study. You may be excluded from participation in this study if you have taken antibiotics in the last 4 weeks.

**8. Alternatives to Participation**

Whether or not you choose to participate in this study you will receive appropriate conventional therapy for your skin lesions.

9. 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 are not obliged to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

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 the Dermatology clinic or the Princess Alexandra Hospital.

Before you make your decision, a member of the research team will be available so that you can ask any questions you have about the research project. You can ask for any information you want. Sign the Consent Form only after you have had a chance to ask your questions and have received satisfactory answers.

**10. What if I withdraw from this research project?**

If you decide to withdraw from this project, please notify a member of the research team before you withdraw. This notice will allow that person or the research supervisor to inform you if there are any health risks or special requirements linked to withdrawing. If you decide to withdraw, and you request it, we will destroy any samples that we may have taken from you and stored for future analysis.

11. How will I be informed of the results of this research project?

On request, a summary of the study results will be sent to you at your last known address on completion of the study. This will **not** include any information which allows identification of participating subjects, and will not therefore include any information that you could recognise as applying to yourself.

12. What else do I need to know?

*What will happen to information about me?*

Any information obtained for the purpose of this research project and for the future research described in section 4 that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as permitted by law. Information about your participation in this research project may be recorded in your health records.

The coded information about the laboratory tests conducted on specimens from subjects in this study will be kept securely until 7 years after the study is completed, as required by the rules governing the conduct of medical research, and then destroyed. The data will be used by the investigators to prepare reports in the medical literature. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. While bacterial cell lines may be prepared from your skin swabs, and may be stored and used in the future, they will not be identifiable as yours, and no personal data will be associated with the cell lines if they are used for future research.

*How can I access my information?*

In accordance with relevant Australian privacy and other relevant laws, you have the right to access the information collected and stored by the researchers about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

***What happens if I am injured as a result of participating in this research project?***

If you suffer an injury as a result of participating in this research project, hospital care and treatment will be provided by the public health service at no extra cost to you if you elect to be treated as a public patient.

*Is this research project approved?*

The ethical aspects of this research project have been approved by the Human Research Ethics Committees of Metro South Hospital and Health Service, and of The University of Queensland.

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

**13. Consent**

I have read, or have had read to me in a language that I understand,this document and I understand the purposes, procedures and risks of this research project as described within it*.* I have had an opportunity to ask questions and I am satisfied with the answers I have received. I freely agree to participate in this research project as described.

I understand that I will be given a signed copy of this document to keep. A copy of the consent form will be sent for scanning into your electronic medical record to comply with GCP requirements.

Participant’s name (printed) ……………………………………………………

Signature Date

Declaration by researcher\*: I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

Researcher’s name (printed) ……………………………………………………

Signature Date

*\* A senior member of the research team must provide the explanation and provision of information concerning the research project. Note: All parties signing the consent section must date their own signature.*

I consent to the storage and use of samples taken from me for use in:

 🞎 this specific research project
 🞎 other research that is closely related to this research project
 🞎 any future research

as described in Section 4 of this document.

Participant's name (printed)………………………………………………………

Signature Date

Researcher's name……………………………………

Signature Date

*Note: All parties signing the consent section must date their own signature.*

**14. Who can I contact?**

Who you may need to contact will depend on the nature of your query, therefore, please note the following:

**For further information or appointments:**

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 :

Name: ***Professor Kiarash Khosrotehrani***

Role: Chief Investigator

Telephone: +61 (0)7 3443 7088

**For complaints:**

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

The HREC Coordinator

Metro South Hospital and Health Service Human Research Ethics Committee

Telephone: 07 3443 8049 and

Email: MSH-Ethics@health.qld.gov.au