MANCHESTER 1824
The University of Manchester

A role for the commensal microbiota in the response of human skin to ultraviolet radiation: Main study

PARTICIPANT INFORMATION SHEET (PIS)

You are being invited to take part in a research study to determine whether bacteria normally living on human skin can alter the responses of human skin to ultraviolet radiation (UVR). Before you decide whether to take part, it is important for you to understand why the research is being conducted and what it will involve. Please take time to read the following information carefully before deciding whether to take part and discuss it with others if you wish. Please ask if there is anything that is not clear or if you would like more information. Thank you for taking the time to read this.

About the research

➢ Who will conduct the research?

This research will be conducted by Miss Wen Duan, Mrs Anne Chandidzura, Dr Mark Farrar, Prof Lesley Rhodes, Prof Andrew McBain and Prof Cath O'Neill, School of Biological Sciences/Health Sciences, Faculty of Biology, Medicine and Health, The University of Manchester.

➢ What is the purpose of the research?

The surface of the skin is colonised with an abundance of microorganisms, collectively termed the skin microbiota, that play a significant role in inhibiting colonisation and activity of potentially dangerous microorganisms, educating the skin immune system, and even contribute to the development of normal skin structure. During the whole life-span of a human, skin cells and skin microorganisms are exposed to the external environment, including ultraviolet radiation (UVR) in sunlight. Since skin microorganisms are important for our skin health, we want to understand their impact on the skin's response to UVR. Previous research has shown that bacteria normally found on human skin have different UVR sensitivity and some may absorb UVR. We have also shown that certain bacteria produce UVR-inducible factors that influence the UVR response of skin cells grown in the laboratory. Therefore, we want to investigate if reducing the number of skin bacteria will impact on UVR-induced effects in human skin such as sunburn and DNA damage. We also want to see what effect UVR has on the numbers of microorganisms present on the skin. The results of this research will help us further understand the role of the normal skin microbiota in skin health. The study will involve a total of 10 healthy white Caucasian volunteers aged 18-40 years.

➢ Am I suitable to take part?

You are suitable to take part in this research if you:

- Are aged 18-40 years of any gender
- Are white Caucasian
- Have NO history of skin sensitivity/allergy to alcohol-based products
- Have NO history of photosensitivity disorder or skin cancer.
- Have NO existing significant (moderate-severe) skin disorder e.g. eczema, psoriasis
- Have NOT used any antibiotics in the past 3 months
- Are NOT taking photoactive, anti-inflammatory or anti-coagulant medication
- Have NOT sunbathed/used a sunbed/received phototherapy in the past 3 months
- Have NOT participated within the last month/are NOT currently participating in other research

➢ Will the outcomes of the research be published?

The outcomes of this project will be published in scientific journals and you will be able to request a copy or a summary of the outcomes from the study team.

➢ Who has reviewed the research project?

This project has been reviewed by the University of Manchester Research Ethics Committee 2.

➢ Who is funding the research project?

This project has been funded by the Biotechnology and Biological Sciences Research Council (BBSRC).

What would my involvement be?

➢ What would I be asked to do if I took part?

Participation requires two visits to the Photobiology Unit, Salford Royal Hospital on consecutive days. The study involves cleaning the skin with 70% ethanol solution, the exposure of small areas of skin to a UVR lamp, and 6 skin samples (punch biopsies). A third visit can be made 7-10 days later for removal of stitches or you can arrange to have this done at your GP practice. All procedures will be performed on the upper back with 3 biopsies taken from the left side and 3 from the right. Local anaesthetic will be given before they are taken and 1 or 2 stitches placed at each site after. Each biopsy is 5mm in diameter as shown here:

If you are interested in taking part, we will ask you some questions by telephone to help determine your suitability (based on the criteria listed above). If you appear suitable, you will be invited to attend a study appointment in which your skin type will be assessed to confirm your suitability. This includes questions on how easily your skin tans or burns, your hair and eye colour, and presence of freckles. You will have the opportunity to ask questions about the study and have them answered. If suitable, and you are happy to proceed, you will be asked to read and sign a consent form.

STUDY VISITS AND PROCEDURES

Visit 1: 1-1.5 hours

The researcher will assess your eligibility to participate in the study and take consent. They will collect demographic and relevant medical information, measure your height and weight, and assess your skin colour using a hand-held device (spectrophotometer). A skin swab will be taken from your left upper back and an area approximately 20x10cm on your right upper back will be cleaned. This will involve gently wiping the area 20 times with 70% ethanol using sterile cotton pads. Following this, the cleaned area of your right upper back will be exposed to a dose-series of UVR to determine your sunburn threshold. The UVR exposure will then be repeated on the uncleaned left side of your upper back. An area of approximately 6x6cm of your left upper back will receive an additional UVR exposure, immediately followed by a swab sample.

Visit 2 (24h after Visit 1): 2 hours

A skin swab will be taken from the 6x6cm area exposed to UVR on Visit 1. Your sunburn threshold on each side of the back will be visually assessed and skin redness measured using a spectrophotometer. A small area of your upper right back will then be cleaned with 70% ethanol (as on Visit 1) and a single 1cm diameter area of this cleaned skin will be exposed to UVR. A single 1cm diameter area on the uncleaned left side will also be exposed to UVR. Following this, 3 skin biopsies will be taken from each

side of the upper back, 2 from UVR-exposed skin sites and 1 from an unexposed site (6 biopsies in total).

Visit 3 (if required, 7-10 days after Visit 2): 15 minutes
Stiches from Visit 2 will be removed.

Your skin samples will be analysed for skin cell DNA damage, and proteins and cells involved in inflammation, cell damage and cell growth. This will not involve genetic analysis (sequencing of your DNA). Your skin swabs will be analysed to determine the number of bacteria on your skin before and after UVR exposure. At the end of the study, if you consent to gift your samples, any remaining samples will be anonymised and retained for use in further related studies. If you do not consent to remaining samples being retained, all samples will be securely destroyed.

Study visits and procedures are summarised below:

Visit 1: 1-1.5 hours
- Consent, demographic & medical information, height, weight, skin colour
- Skin swab taken from left upper back
- Right upper back cleaned with 70% ethanol
- UVR dose series applied to both sides of upper back
- Single UVR exposure applied to left upper back
- Skin swab taken from left upper back

Visit 2 (24h after Visit 1): 2 hours
- Skin swab taken from left upper back
- Assessment of sunburn threshold
- Small area of right upper back cleaned with 70% ethanol
- Single UVR dose applied to cleaned area and to uncleaned left upper back
- 6 skin biopsies taken

Visit 3: (7-10 days after Visit 2): 15 minutes
- Removal of stitches

➢ What are the possible disadvantages or risks of taking part?

We do not expect there to be any disadvantage from taking part. You will experience redness and possibly some discomfort of the skin exposed to UVR. Some discomfort will be felt at the time of skin biopsy and in the days following, which may include redness, irritation, and pain at the site. There is also a small risk of infection and bleeding, and of intolerance or allergy to the local anaesthetic. You will be given wound care advice and should avoid strenuous exercise during the period.

A small permanent scar will be left on your skin at each biopsy site.

If you do suffer these or any other symptoms or have any concerns following the skin biopsy procedure you should contact the research team on 0161 2060457 during office hours. Out of hours you can contact the on-call dermatologist via the Salford Royal Hospital switchboard (0161 7897373).

➢ Will I be compensated for taking part?

In view of the time, travelling and inconvenience involved in taking part in this study, volunteers completing the study will receive reimbursement of £200. If you do not complete the study, reimbursement will be pro-rata based on the number of visits made and samples provided. Payment will be made by bank transfer.

➢ What happens if I do not want to take part or if I change my mind?

Participation is entirely voluntary and it is up to you to decide whether or not to take part. Please contact a member of the research team by phone or email to let them know if you want to participate or not – contact details are at the end of this document. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time without giving a reason and without detriment to yourself. However, it will not be possible to remove your data from the project once it has been anonymised as we will not be able to identify your specific data. This does not affect your data protection rights. If you decide not to take part you do not need to do anything further.

➢ What happens if I lose capacity to consent?

If, after giving informed consent, you then lose capacity to consent, you will be withdrawn from the study. Any identifiable data or tissue already collected with consent would be retained and used in the study but no further data or tissue would be collected or any other research procedures carried out.

Data Protection and Confidentiality

➢ What information will you collect about me?

In order to participate in this research project, we will need to collect information that could identify you, called "personal identifiable information". Specifically, we will need to collect your:

1. Name
2. Gender
3. Ethnicity
4. Date of birth
5. Contact details (address, email, phone)

➢ Under what legal basis are you collecting this information?

We are collecting and storing this personal identifiable information in accordance with UK data protection law which protect your rights. These state that we must have a legal basis (specific reason) for collecting your data. For this study, the specific reason is that it is "a public interest task" and "a process necessary for research purposes".

➢ What are my rights in relation to the information you will collect about me?

You have a number of rights under data protection law regarding your personal information. For example, you can request a copy of the information we hold about you.
If you would like to know more about your different rights or the way we use your personal information to ensure we follow the law, please consult our Privacy Notice for Research.
The full URL of the privacy notice can be found from:
http://documents.manchester.ac.uk/display.aspx?DocID=37095

➢ Will my participation in the study be confidential and my personal identifiable information be protected?

In accordance with data protection law, The University of Manchester is the Data Controller for this project. This means that we are responsible for making sure your personal information is kept

secure, confidential and used only in the way you have been told it will be used. All researchers are trained with this in mind, and your data will be looked after in the following way:

Only the study team at The University of Manchester will have access to your personal information, but they will anonymise it as soon as possible. Your name and any other identifying information will be removed and replaced with a random ID number. Only the research team will have access to the key that links this ID number to your personal information. Your consent form will be retained for 5 years in a locked cabinet on UoM premises for audit purposes. With your consent, we would also like to retain your contact details for 5 years in order to provide you with a summary of the findings for this study and also to inform you about future studies that you may be interested in. If you provide consent for this, your details will be safely stored on UoM servers in a digital folder only accessible to the study team and used only for the purposes described above.

Please also note that individuals from The University of Manchester or regulatory authorities may need to look at the data collected for this study to make sure the project is being carried out as planned. This may involve looking at identifiable data. All individuals involved in auditing and monitoring the study will have a strict duty of confidentiality to you as a research participant.

What if I have a complaint?

If you have a complaint that you wish to direct to members of the research team, please contact:

Wen Duan
Tel: 0161 275 4786
Email: wen.duan@manchester.ac.uk

If you wish to make a formal complaint to someone independent of the research team or if you are not satisfied with the response you have gained from the researchers in the first instance then please contact:

The Research Ethics Manager, Research Office, Christie Building, The University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 306 8089.

If you wish to contact us about your data protection rights, please email dataprotection@manchester.ac.uk or write to The Information Governance Office, Christie Building, The University of Manchester, Oxford Road, M13 9PL at the University and we will guide you through the process of exercising your rights.

You also have a right to complain to the Information Commissioner's Office about complaints relating to your personal identifiable information Tel: 0303 123 1113. The full URL of the ICO's complaints procedure can be found from: https://ico.org.uk/

Additional information in relation to COVID-19

Due to the ongoing COVID-19 pandemic, we have made some adjustments to the way in which this research study will be conducted that ensures we are adhering to the latest government advice and taking all reasonable precautions in terms of limiting the spread of the virus. You should carefully consider all of the information provided below before deciding if you still want to take part in this research study. If you choose not to take part, you need to inform research team. If you have any additional queries about any of the information provided, please speak with a member of the research team.

Are there any additional considerations that I need to know about before deciding whether I should take part?
As this project will be conducted face-to-face, it is still possible to catch and spread COVID-19 though travelling and contact with other people.

What additional steps will you take to keep me safe while I take part?
Steps will be taken to reduce the chance of coming into contact with and/or spreading the virus, including:
1） face coverings will be required during all the procedures;
2） all research members will be fully vaccinated;
3） all the equipment used in this project will be disinfected before usage;
4） single use equipment (i.e., pens, post-its, etc) will be provided to each participant;
5） hand sanitizer will be provided to enable researchers and participants to clean their hands more frequently;
6） PPE will be used properly.

Is there any additional information that I need to know?
Please arrive on time (not early or late) to avoid too many participants gathering in the same area. Face coverings will be required during all the procedures.

What if the Government Guidance changes?
We will comply with the government guidance on activity for conducting clinical projects. The guidance will be checked regularly by the research team. Participants will be informed any changes or postponements at the earliest time.

Contact Details

If you have any queries about the study or if you are interested in taking part then please contact a member of the research team:

Anne Chandidzura, Senior Research Nurse

Tel: 0161 206 0457

E-mail: anne.chandidzura@manchester.ac.uk

or

Wen Duan, Research Associate

Tel: 0161 275 4786

E-mail: wen.duan@manchester.ac.uk