MANCHESTER 1824
The University of Manchester

Salford Royal NHS
NHS Foundation Trust
University Teaching Hospital

AGE-RELATED ABILITY TO SYNTHESISE VITAMIN D IN THE SKIN ON EXPOSURE TO SUNLIGHT

Participant Information Sheet

You are being invited to take part in a research study being sponsored by The University of Manchester. Before you decide whether or not you wish to take part, it is important that you understand why the study is being performed and what it would involve for you. Please take time to read the following information carefully. One of our research team will go through it with you and answer any questions you have. Discuss the study with your friends, family or General Practitioner if you wish. Please ask if anything is not clear or you would like more information. Thank you for taking the time to read this.

Who will conduct the research?

This research will be conducted by Oktawia (Octavia) Borecka, PhD Researcher in Skin Photobiology, School of Earth and Environmental Sciences, Faculty of Science & Engineering, The University of Manchester.

What is the purpose of the research?

The purpose of this study is to see if there is a difference between young and older adults in how much Vitamin D their skin is able to produce in response to sunlight. We get most of our vitamin D through exposure to ultraviolet (UV) in sunlight and a small amount from our diet. When skin exposed to sunlight, a molecule called 7-DHC is converted to vitamin D which then enters the bloodstream. We want to see how much 7-DHC you have in your skin and how much vitamin D you make through exposure simulated sunlight (UV) exposure. The study will be conducted between May 2018 and February 2019.

Why have I been chosen?

This research will involve up to 24 healthy male and female adults aged 18-40 or 65-89 years. We are inviting you to take part in this research as you are within one of these age ranges.

Do I have to take part in this study?

Participation in this study is entirely voluntary and will require you to agree to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. You can withdraw from the study at any time without giving a reason. If you do withdraw from the study, information gathered to that point may still be used in the research (with your consent), but no additional information will be collected. Should you lose the capacity to consent during the course of the study, you will be withdrawn from the study. Your data and samples already collected (including identifiable data) will be retained for use in the study, but no further data or samples would be collected

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

This study involves four visits to the Photobiology Unit: one for consent and baseline assessments, then three visits for the research procedures.

If you are suitable you will be invited to attend an initial visit in which you will have the opportunity to ask questions and have them answered. You will then be asked to sign a Consent form. We will then assess your skin type and take height and weight measurements.

Your second visit will take up to 1 hour. A blood sample will be taken following which you will be asked to change into standardised clothing (surgical scrubs) which we will provide. The clothing represents a T-shirt and shorts so that your hands, arms, lower legs and face are exposed. There will be a 5 cm x 5 cm cut out area in the shorts to expose an area of your upper buttock from which we will take skin samples. Your skin colour will be measured using a non-invasive handheld instrument. You will then be given a low dose of UV in a whole body cabinet. Immediately following the UV exposure four skin samples will be taken, two from the exposed area of upper buttock and two from a covered area of upper buttock. When all procedures have been completed, we will provide you with a vitamin D diet diary and a lifestyle questionnaire for you to fill in and return on your final visit. You will also be provided with a standard NHS skin biopsy aftercare leaflet.

You will attend 24h later for a blood sample and two further skin samples will be taken from the UV-exposed area of upper buttock.

On your final visit you will return the completed diary and questionnaire and a final blood sample will be taken. The research nurse will also remove the stitches from the skin sample sites

Baseline assessments

Your height and weight will be taken to calculate BMI. Your skin type will also be assessed using a non-invasive handheld instrument.

Blood samples

Blood samples will be approximately 20 ml (just over one tablespoon) and will be used to assess your vitamin D level and your general blood biochemistry including calcium level, and liver and kidney function.

Skin samples

Skin biopsies, six in total, will be taken from the upper buttock, and will be used to assess levels of 7-DHC and vitamin D. Biopsies will be 5 mm (3/16”) in diameter and about the same depth. This is approximately the width of a pencil as shown here: ●

The skin biopsy procedure

1. The area is cleaned with an alcohol swab and
2. The skin is numbed using a local anaesthetic injection.
3. An instrument called a punch is used to remove a small circle of skin.
4. The site will be closed with one stitch and a dressing applied.

5. You will be advised to avoid strenuous activity for 7 days.
6. You will need to avoid getting water on the site where your biopsy was taken for 48 hours.

Study flow diagram:

Visit 1. Consent and baseline assessments

Visit in Photobiology Unit:

- Informed consent
- Assessment of your skin type
- Height and weight measurements

Visit 2. UV Exposure

Visit in Photobiology Unit:

- Blood sample taken
- Skin exposed to UV in an irradiation cabinet
- Up to four skin biopsies taken
- Receive diary and questionnaire

Visit 3. 24h after visit 2

Visit in Photobiology Unit:

- Blood sample taken
- Up to two skin biopsies taken

Visit 4. 1 week after visit 2

Visit in Photobiology Unit:

- Blood sample taken
- Removal of biopsy stiches
- Return of diary and questionnaire

Over a seven day period

What are the possible disadvantages or risks of taking part?

We do not expect there to be any disadvantage from taking part. There may be slight discomfort and bruising following the blood sample. The injection used to numb the skin prior to the sample being taken may feel uncomfortable, similar to a bee sting. There might be some discomfort and bleeding from the biopsy site during and after the procedure. As with any invasive procedure, there is a small chance that the wound may open or that it may become infected. After the stitches have been removed there will be a small pink line or mark on your skin, which will fade over time.

You will be left with a small permanent scar at each biopsy site.

If you have any concerns following the skin sample procedure then you should contact the unit during office hours or the on-call dermatologist out of hours through the SRFT switchboard 0161 789 7373.

What happens to the data collected?

The results of this study will help guide future research and may help inform national guidance on sunlight exposure.

How is confidentiality maintained?

All information given to us and results obtained will be kept in the strictest confidence and will only be accessed by the researchers working on this study, by people from regulatory authorities and The University of Manchester and Salford Royal Foundation Trust to check the study is being carried out correctly. Our collaborator at the University of East Anglia will have access to anonymised samples which will be transported at UEA facilities for analysis, however all person information will be stored at the University of Manchester.

Your name and other personal information will not be disclosed other than to inform your GP that you are taking part in the study (with your consent). Blood and skin samples will be stored anonymously under the Human Tissue Authority licence of the University or NHS Trust as appropriate. All records will be held in the locked offices at the University of Manchester.

What happens to my data?

All electronic data will be stored and backed up daily on secure University of Manchester servers. Personal data will be stored for 5 years after the last publication of the study or for 10 years, whichever is the greater, and will only be accessed by the research team and members of the University of Manchester, Trust and regulatory authorities for auditing and monitoring purposes. Consent forms will be retained for 5 years following the end of study. Anonymised samples will be retained for future research.

We are collecting and storing this personal information in accordance with the General Data Protection Regulation (GDPR) and Data Protection Act 2018 which legislate to protect your personal information. The legal basis upon which we are using your personal information is “public interest task” and “for research purposes” if sensitive information is collected. For more information about the way we process your personal information and comply with data protection law please see our Privacy Notice for Research Participants.

What happens to my samples?

If you give consent to gift your samples for use in future research (pending further ethical approval), they will be anonymised and stored under license at the University of Manchester in accordance with Human Tissue Authority regulations. If you have opted not to gift your samples they will be destroyed when the study is complete.

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

Participation in this study is entirely voluntary and will require you to agree to take part. If you do decide to take part you will be given this information sheet to keep and you will be asked to sign a consent form. If you do decide to take part you can withdraw from the study at any time without giving a reason. If you do withdraw from the study, information gathered to that point may still be used in the research (with your consent), but no additional information will be collected. Should you lose the capacity to consent during the course of the study, you will be withdrawn from the study. Your data and samples already collected (including identifiable data) will be retained for use in the study, but no further data or samples would be collected. Optionally, your samples can also be used in future related studies pending further ethical approval.

Will I be paid for participating in the research?

Volunteers completing the study will receive reimbursement of **£250** (£25 for each biopsy, £10 for each blood sample and £70 for travel expenses). Reimbursement is for travel costs, which is made at a flat rate, and for the time and inconvenience of taking part. If a volunteer does not complete the study, reimbursement will be pro-rata based on the number of visits made and samples provided.

Where will the research be conducted?

The research will be conducted in the Photobiology Unit, Barnes Building, Salford Royal NHS Foundation Trust.

Will the outcomes of the research be published?

The results of this research will be published in scientific journals, including specialist dermatology and general science journals, and presented at conferences. If you would like a copy of any research publications relating to this study or a summary of the results then please make the study team aware of this. You will not be identified in any publication of these results.

Disclosure and Barring Service (DBS) Check

The University of Manchester researchers have all been subject to a DBS check and have been given permission to conduct research on the Trust premises.

Who has reviewed the research project?

This study has been reviewed by the Biotechnology and Biological Sciences Research Council (BBSRC), which is funding this research. The study has also been reviewed and approved by a University of Manchester Research Ethics Committee.

What if something goes wrong?

If you have any concerns or there is a problem then please contact the research team on 0161 206 0457. They will be able to advise you

Statement of Indemnity

In the event that something does go wrong and you are harmed during the research you may have grounds for a legal action for compensation against the University of Manchester or NHS Trust but you may have to pay your legal costs

What if I want to make a complaint?

Minor complaints

If you have a minor complaint then you need to contact the researcher(s) in the first instance

Mrs Joanne Osman. Tel: 0161 2060457. E-mail: joanne.osman@manchester.ac.uk
Ms Oktawia Borecka. E-mail: oktawia.borecka@postgraduate.manchester.ac.uk
Prof Lesley Rhodes. Tel: 0161 206 1150 E-mail: lesley.e.rhodes@manchester.ac.uk

Formal Complaints

If you wish to make a formal complaint or if you are not satisfied with the response you have gained from the researchers then please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

What Do I Do Now?

If you have any queries about the study or if you are interested in taking part then please contact the researcher(s):

Joanne Osman, Research Nurse Tel: 0161 2060457.
E-mail: joanne.osman@manchester.ac.uk

Thank you for taking the time to read this information.
If you decide to take part in the study please keep a copy of this for your information.

This Project Has Been Approved by the Greater Manchester West NHS Research Ethics Committee [reference number 18/NW/0493].