MANCHESTER 1824

The University of Manchester

Salford Royal NHS
NHS Foundation Trust
University Teaching Hospital

PARTICIPANT INFORMATION SHEET

DAMAGE AND REPAIR FOLLOWING REAL LIFE SUN EXPOSURE: IDENTIFYING THE IMPACT OF SOLAR UV EXPOSURE ON SKIN AND THE DYNAMICS OF ITS REPAIR

You are invited to take part in a research study funded by Walgreens Boots Alliance. 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 read this information sheet carefully. If you have questions relating to this information sheet, please contact Dr Rachel Watson who is leading the research project (University of Manchester – 0161 275 5505 / Dermatopharmacology Unit, Salford Royal Teaching Hospital – 0161 206 0889) - she will be pleased to discuss the study with you. If you decide to take part, one of our research team will go through it with you and answer any further questions you might 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.

What is the purpose of this study?
Skin damage happens because of our exposure to sunshine over many, many years. We have found that proteins in our skin, the collagens and elastic fibres, are damaged when skin is exposed to sunlight. We want to know how much damage happens to skin following a typical summer beach holiday and how quickly the skin recovers after we return home.

Why have I been invited to take part?
This study will involve healthy male and female adults, aged between 18 and 45 years of age from Greater Manchester.

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 but no additional information will be collected.

What will happen to me if I take part?
If you decide to take part, you will be asked to visit the clinic ten times over a period of 4 months. The study will be conducted as follows:

At the first visit, the research nurse will ask you some questions about your general health and discuss the study with you in detail. You will then be given a small device called a dosimeter – this measures the amount of sunlight you are exposed to. The second visit will be 2 weeks later; at this visit, we will replace your dosimeter and assess your skin by measuring its colour and by taking a high quality photograph of your face using a special camera system called VISIA®. At this visit we will also take a small blood sample from you (10 mls, equivalent to 2 teaspoons), a swab of your skin to see how much skin damage you have previously received, a sample of the very topmost layer of your skin (using a sticky

tape) and take two small skin samples (biopsies), one from an area which is rarely exposed to the sun (buttock) and one sun exposed area (forearm). The skin biopsy procedure is as follows: each site will be numbed with a small amount of local anaesthetic and a small 3 mm diameter skin biopsy (●) will be taken with an instrument similar to a biscuit cutter. This biopsy samples all of the layers of the skin, to a depth of about ½ cm. The biopsy site will be closed with a stitch and local dressings supplied. We will take the stiches out between 7-10 days later (visit 3) at the Dermatopharmacology Unit, Salford Royal Teaching Hospital. At this visit, we will discuss with you how to protect yourself from sun damage whilst you are on holiday and may provide you with a sunscreen product (supplied by Walgreens Boots Alliance). We will also give you a new dosimeter and a simple sun exposure diary to complete whilst away. This is the final visit before your summer beach holiday.

On the day after you return to the UK, we will ask you to come back to clinic. At this visit please bring in all your bottles of sunscreen, so we can estimate how much product you used whilst on holiday. We will also take in your dosimeter and your sun exposure diary and we will repeat the measures described above (visit 4). The next visit will be in 7 days' time; we will remove the stitch from the previous biopsy sample and repeat the biological measures (visit 5; stitch removed in 7-10 days, visit 6). The next visit will be a month after you have returned off holiday – again we will repeat all of our measures (visit 7; stitch removal in 7-10 days, visit 8). The final sampling will be 3 months after you return from holiday (visit 9; stich removed in 7-10 days, visit 10). The schedule of visits is outlined below for your convenience.

Visit number	Procedure
1	Discuss the study; Take informed consent; Provide dosimeter to measure your exposure to sunlight.
2	Refresh dosimeter to measure your exposure to sunlight Skin assessment (CR-400, VISIA®-CR); Biological sampling (skin swab, tape strips, 10ml blood sample, baseline biopsies from buttock & forearm).
3	Refresh dosimeter to measure your exposure to sunlight Remove stiches; Provide sunscreen/note product to be used; Supply sun exposure/sunscreen use diary.
	Depart on holiday (14 days)
4	Return dosimeter; weigh sunscreen bottles; take in sun exposure/sunscreen diaries; Skin assessment (CR-400, VISIA®-CR); Biological sampling (skin swab, tape strips, blood sample, +1 day biopsy from forearm).
5	Skin assessment (CR-400, VISIA®-CR); Biological sampling (skin swab, tape strips, blood sample, +7 day biopsy from forearm); Remove sutures from +1 day biopsy site.
6	Remove sutures from +7 day biopsy site.
7	Skin assessment (CR-400, VISIA®-CR); Biological sampling (skin swab, tape strips, blood sample, +28 day biopsy from forearm).
8	Remove sutures from +28 day biopsy site.
9	Skin assessment (CR-400, VISIA®-CR); Biological sampling (skin swab, tape strips, blood sample, +84 day biopsy from forearm).
10	Remove sutures from +84 day biopsy site.

If you have any concerns or queries during the visits, Dr Rachel Watson (lead researcher) or Sr Gill Aarons will be able to answer them.

The information taken during visits will be stored on encrypted University of Manchester computers. As information is gathered, your data will be given a unique number to identify it to researchers – this allows you to remain anonymous throughout the data collection period and when the data is being analysed; this includes the clinical photographs taken using the VISIA® system. All of your anonymous data and any remaining biopsy tissue will be stored for 10 years. The findings of the experiments will be shared with Walgreens Boots Alliance.

What are the possible disadvantages or risks of taking part?
We do not expect there to be any adverse effect from your taking part. Some discomfort will be felt at the time of skin biopsy and in the days following this procedure, which may include redness, irritation and pain at the site. A small permanent scar will be left on your skin at each biopsy site. There is also a small risk of infection and bleeding with biopsies, as with all minor skin surgery. If you do suffer these or any other symptoms you should report them to the study nurse.

What are the possible benefits of taking part?
You will not benefit directly from taking part in this study.

Will I be reimbursed for this study?
In view of the time, travelling and inconvenience involved in taking part in this study, you will receive reimbursement of £350. Should you decide to not complete the study, you will receive pro rata compensation for your time and inconvenience.

What will you do to my tissue sample?
Your tissue sample will be examined which important proteins known to be damaged by sunlight. The samples will be analysed by scientists at the University of Manchester. With your consent, skin samples will be given to the University and may be used in other studies of skin ageing. At the end of the study, your tissue samples will be transferred to the Dermatology tissue collection, which is monitored by the University of Manchester Governance, Research and Integrity Office in compliance with the Human Tissue Act (2004).

What will happen to the results of the study?
The results will be published and you will be able to obtain a summary of this from the study team. You will not be identified in any publication of these results.

Will my taking part in this study be kept confidential?
If you consent to take part in the research, your hospital medical records may be looked at by the medical staff involved in the study and by people from regulatory authorities to check that the study is being carried out properly. Your name however will not be disclosed outside the hospital. The information gathered during this study will have your name removed from it so that there will be no way of identifying you from the information that is collected.

Who is organising and funding the research?
The study is being organised by the Dermatopharmacology Unit, Salford Royal Hospital, Manchester and your skin biopsies will be analysed at the Dermatology research laboratories at the University of Manchester. Walgreens Boots Alliance is funding this research. If you would like a copy of the results, please contact Dr Rachel Watson.

Who has reviewed this study?
This study has been reviewed by the study team at the University of Manchester. The study has also been reviewed and approved by the University of Manchester Research Ethics Committee 1.

Contact for further information

Please contact Dr Rachel Watson for further information about this study (University of Manchester – 0161 275 5505 / Dermatopharmacology Unit, Salford Royal Teaching Hospital – 0161 206 0889). If you have any questions, have experienced a research-related injury, or have any problems at any time during the study you can contact one of the study investigators at Salford Royal Teaching Hospital on 0161 206 1043. In the event of an emergency you should contact the on-call dermatologist at Salford Royal Hospital on 0161 789 7373.

If you have any concerns regarding this study that the research team are unable to resolve, or which you prefer not to raise with them directly, please contact the University Research Governance, Ethics and Integrity Manager on 0161 275 2046 or 0161 275 2674 or by email to research.complaints@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
University of Manchester's Research Ethics Committee 1, ref 16302