

# Biomarkers of ultraviolet radiation exposure

<b>Submission date</b> 19/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 19/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 26/10/2022	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Sunshine has both positive and negative effects on health. Humans require sunlight to manufacture vitamin D in the skin however too much sun exposure can cause DNA damage, photo aging and skin cancer. Products of DNA damage repair are excreted in urine making them potentially useful indicators of sunlight exposure and hence risk of skin cancer. This study aims to validate DNA damage in urine as a marker of ultraviolet rays (UVR)-induced skin DNA damage. We will also assess the applicability of urinary DNA damage to assessment of the risk (DNA damage) versus benefit (vitamin D production) of UVR exposure.

### Who can participate?

This study will involve healthy male and female adults of all skin types, aged 18-45 years from Greater Manchester.

### What does the study involve?

Subjects will first have their sunburn threshold determined then will receive a single, whole body (exposing 35% skin surface area) exposure below this threshold, mimicking a short exposure to sunlight on a summers day. Subjects will then collect their urine for five days which will be tested for products of DNA damage. In the second part of the study, subjects will receive four increasing doses of UVR (all below their sunburn threshold), separated by 1 month. Urine and skin biopsy samples will be taken before and after exposure to examine for DNA damage. In addition, blood samples will be taken before and after exposure for vitamin D analysis.

### What are the possible benefits and risks of participating?

This study will not provide direct benefit to research participants. However, if any participant taking part is found to have vitamin D levels defined as deficient, their GP will be notified in order that appropriate treatment/advice may be given. Following UVR exposure for sunburn threshold testing, transient redness will be experienced on the exposed area. Tanning of the skin may occur in areas where UVR has been applied. Slight discomfort or bruising may be experienced during blood sampling but this is minimised by using experienced venepuncture practitioners. Skin biopsies on the buttocks may result in small permanent scars.

### Where is the study run from?

Photobiology Unit, Salford Royal NHS Foundation Trust.

When is the study starting and how long is it expected to run for?

This study will run from June 2012 for 30 months.

Who is funding the study?

Cancer Research UK

Who is the main contact?

Jessica Edwards, Research Associate [jessica.edwards@manchester.ac.uk](mailto:jessica.edwards@manchester.ac.uk)

<https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-measuring-the-risks-and-benefits-of-exposure-to-sunlight>

## Contact information

### Type(s)

Scientific

### Contact name

Prof Lesley Rhodes

### ORCID ID

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### Contact details

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## Additional identifiers

### Protocol serial number

12049

## Study information

### Scientific Title

Biomarkers of ultraviolet (UVR) exposure: tools for determining the relationship between the benefits and hazards of UVR

### Study objectives

Urinary DNA damage repair products are ideal biomarkers of UVR exposure and are potential intermediate biomarkers for skin cancer risk, as their presence in urine is related to both UVR exposure and DNA repair.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

University of Manchester Research Ethics Committee, 06/12/2011, ref: 11266

**Study design**

Experimental study

**Primary study design**

Interventional

**Study type(s)**

Diagnostic

**Health condition(s) or problem(s) studied**

Topic: Skin; Subtopic: Skin (all Subtopics); Disease: Dermatology

**Interventions**

Participants exposing approximately 35% skin surface area will receive a single, whole body exposure to UVR of 0.8 MED. Urine collected over the following 5 days will be analysed to determine the time of maximal DNA damage product concentration. Participants will then receive 4 increasing whole body doses of UVR (0.2-0.8 MED) each separated by 1 month. DNA damage in urine collected at the optimal time point and in skin biopsies taken immediately and 48 h after exposure will be compared to that in samples taken pre-exposure. Serum 25(OH)D will also be assessed.

**Intervention Type**

Other

**Phase**

Not Applicable

**Primary outcome(s)**

Urinary DNA damage; Timepoint(s): Up to 14 days post exposure

**Key secondary outcome(s))**

1. Time of maximal DNA damage product concentration in urine following acute UVR exposure
2. Minimum dose of UVR required to produce detectable levels of DNA damage in urine
3. Level of DNA damage in skin biopsy sections following acute UVR
4. Concentration of serum 25(OH)D following acute UVR exposure

**Completion date**

31/05/2014

**Eligibility****Key inclusion criteria**

1. Healthy, ambulant human volunteers
2. Aged 18-45 years

3. Sun reactive skin types I-VI
4. Non smokers
5. Body mass index (BMI) of less than 30

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Upper age limit**

45 years

**Sex**

All

**Total final enrolment**

65

**Key exclusion criteria**

1. History of skin cancer or photosensitivity disorder
2. Taking photoactive medication
3. Sunbathing or sunbed use in the past 3 months
4. Taking dietary supplements containing vitamin D or antioxidants

**Date of first enrolment**

16/04/2012

**Date of final enrolment**

31/05/2014

## **Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Photobiology Unit**

Salford

United Kingdom

M6 8HD

# Sponsor information

## Organisation

University of Manchester (UK)

## ROR

<https://ror.org/027m9bs27>

# Funder(s)

## Funder type

Charity

## Funder Name

Cancer Research UK (UK)

## Alternative Name(s)

CR\_UK, Cancer Research UK - London, Cancer Research UK (CRUK), CRUK

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Other non-profit organizations

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

Not provided at time of registration

## IPD sharing plan summary

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/10/2018	22/01/2019	Yes	No
<a href="#">Participant information sheet</a>	Participant information sheet	11/11/2025	11/11/2025	No	Yes

