# Biomarkers of ultraviolet radiation exposure

Submission date 19/07/2012	<b>Recruitment status</b> No longer recruiting	Prospectively registered	
		[_] Protocol	
Registration date 19/07/2012	<b>Overall study status</b> Completed	[] Statistical analysis plan	
		[X] Results	
Last Edited 26/10/2022	<b>Condition category</b> Skin and Connective Tissue Diseases	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

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

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# Additional identifiers

EudraCT/CTIS number

**IRAS number** 

ClinicalTrials.gov number

Secondary identifying numbers 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

**Secondary study design** Non randomised study

#### Study setting(s) Other

#### **Study type(s)** Diagnostic

#### Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

#### 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 measure

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

#### Secondary outcome measures

- 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

## Overall study start date

16/04/2012

# **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

**Age group** Adult

**Lower age limit** 18 Years

Upper age limit

45 Years

**Sex** Both

### Target number of participants

Planned Sample Size: 75; UK Sample Size: 75

### 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** England

United Kingdom

**Study participating centre Photobiology Unit** Salford United Kingdom M6 8HD

# Sponsor information

**Organisation** University of Manchester (UK)

**Sponsor details** FMHS Research Office 3.53 Simon Building Manchester England United Kingdom M13 9PT

**Sponsor type** University/education

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, CRUK

**Funding Body Type** Private sector organisation

**Funding Body Subtype** Other non-profit organizations

**Location** United Kingdom

# **Results and Publications**

### Publication and dissemination plan

Not provided at time of registration

Intention to publish date

#### **Individual participant data (IPD) sharing plan** Not provided at time of registration

#### IPD sharing plan summary

Not provided at time of registration

#### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<u>Results article</u>	results	01/10/2018	22/01/2019	Yes	No
<u>Plain English results</u>			26/10/2022	No	Yes