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Biomarkers of ultraviolet radiation exposure

Submission date
19/07/2012

Recruitment status
No longer recruiting

Registration date
19/07/2012

Overall study status
Completed

Last Edited
26/10/2022

Condition category
Skin and Connective Tissue Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Contact name
Prof Lesley Rhodes

ORCID ID
https://orcid.org/0000-0002-9107-6654

Contact details
Photobiology Unit
Dermatology Centre
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD
+44 161 306 6000
lesley.e.rhodes@manchester.ac.uk

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?
Results article	results	01/10/2018	22/01/2019	Yes	No
Plain English results			26/10/2022	No	Yes