

Sun exposure for vitamin D sufficiency in skin type V

Submission date 12/05/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/05/2010	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 26/04/2013	Condition category Skin and Connective Tissue Diseases	<input type="checkbox"/> Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
5625

Study information

Scientific Title

Sun exposure levels for provision of vitamin D sufficiency in people of skin type V living in the UK

Study objectives

1. What is the effect on vitamin D status in people of skin type V, of the amount of UV exposure recommended for white Caucasian subjects, and how much extra UV exposure do skin type V people require?

Intervention study:

A UV course will be given to 60 subjects in January/February, using a whole body cabinet with lamps emitting a UV spectrum similar to sunlight. Blood 25(OH)D levels measured weekly.

2. What levels of vitamin D are attained through natural sunlight exposure in skin type V individuals living in the UK? How do these relate to personal UV exposure doses? Does the relationship differ from that in white Caucasian individuals?

Observation study:

125 subjects will have blood 25(OH)D levels assessed once in each season, UV exposure measured through polysulphone badges and dietary vitamin D assessed through diet diaries.

The results of the experimental work in the intervention study can be related to the findings of the real population in the observation study. Moreover, both studies in skin type V volunteers can be related to the findings of the equivalent studies in the white Caucasian subjects.

Ethics approval required

Old ethics approval format

Ethics approval(s)

North Manchester Research Ethics Committee approved on the 20th May 2008 (ref: 08/H1006/24)

Study design

Single centre non-randomised prevention and treatment trial

Primary study design

Observational

Secondary study design

Single-centre

Study setting(s)

Hospital

Study type(s)

Treatment

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

1. Intervention study:

1.1. Subjects were given simulated summer's sun exposures from a constant UVR dose via a full body cabinet, 3 times a week for 6 weeks. The subjects were split into 6 groups receiving either 0.65, 1.3 1.95, 2.6, 3.2, 3.9 SED. This was given in Jan/Feb, when there is no confounding ambient UVR

1.2. Vitamin D (25(OH)D) blood samples were taken pre-intervention and then weekly for 6 weeks

1.3. Patients completed diet diaries (1st week and 6th week) to assess dietary vitamin D

2. Observational study:

2.1. Vitamin D (25(OH)D) blood samples were taken in each season of the year (April - Spring, July - Summer, October - Autumn, January - Winter)

2.2. The subjects were also given polysulphone film badges to wear on their clothes for one week in each season to measure ambient UV

2.3. Sun exposure diaries were also used to give additional information about seasonal UV exposure

2.4. A diet diary was completed in each season for dietary vitamin D assessment.

Follow up was for one year.

The interventional follow up was for 7 weeks, the actual intervention (not treatment) was carried out over 6 weeks.

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Vitamin D

Primary outcome measure

1. Intervention study: % number of people reaching sufficient levels of vitamin D following simulated summer exposure

2. Observational study: the post summer vitamin D level required to maintain sufficiency throughout the winter months

Secondary outcome measures

Interventional study:

1. The % numbers reaching optimal levels of vitamin D following simulated summer sun exposure

2. Baseline winter levels of vitamin D deficiency, sufficiency and optimal levels

Overall study start date

01/09/2008

Completion date

30/05/2009

Eligibility

Key inclusion criteria

1. Aged 18 - 65 years old
2. South Asian descent
3. Male or female
4. Sun-reactive skin type V
5. Ambulant

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned sample size: 185

Key exclusion criteria

1. History of skin cancer (intervention study)
2. History of a photosensitivity disorder (both)
3. Regular sunbathing/use of sunbeds (observational study)
4. Sunbathing/use of sunbeds in the past 3 months (intervention study)
5. Taking photoactive medication (interventional)
6. Pregnant or breast-feeding (interventional)

Date of first enrolment

01/09/2008

Date of final enrolment

30/05/2009

Locations

Countries of recruitment

England

United Kingdom

Study participating centre
Photobiology Unit
Salford
United Kingdom
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Sponsor information

Organisation

University of Manchester (UK)

Sponsor details

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Sponsor type

University/education

Website

<http://www.manchester.ac.uk>

ROR

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

Funder(s)

Funder type

Charity

Funder Name

Cancer Research UK (CRUK) (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****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/11/2011		Yes	No
Results article	results	01/06/2013		Yes	No