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Sun exposure for vitamin D sufficiency in skin type V

Submission date	Recruitment status	[_] Prospectively registered
12/05/2010	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
12/05/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
26/04/2013	Skin and Connective Tissue Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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)

Primary study design
Observational

Study design
Single centre non-randomised prevention and treatment trial

Study type(s)
Treatment

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(s)
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

Key secondary outcome(s)
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

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

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 Years

Sex
All

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
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 (CRUK) (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

IPD sharing plan summary

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