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Limited skin areas and vitamin D

Submission date	Recruitment status	[_] Prospectively registered
04/02/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
04/02/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
08/02/2015	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Vitamin D is essential for healthy bones. Calcium and phosphorus are essential for bone growth and also to strengthen bones and we need vitamin D to absorb these minerals. People get most of their vitamin D though exposure to sunlight. National guidance on requirements for vitamin D assume that casual exposure of limited areas of skin to summer sunlight is sufficient to avoid vitamin D deficiency. Previous studies have shown that a six week course of exposures to simulated summer sunlight while casually dressed (shorts and T-shirt) can produce adequate vitamin D levels in the majority of the UK white Caucasian population. The aim of this study is to determine if exposure of more limited areas of skin can produce a sufficient rise in vitamin D levels to avoid deficiency.

Who can participate?
Healthy white Caucasian adults, aged between 20-60.

What does the study involve?
Volunteers undergo a six week course of simulated sunlight (ultraviolet light) exposures, wearing clothes that expose small areas of skin (hands and face).

What are the possible benefits and risks of participating?
Participants will not benefit directly from taking part in this study. However, if they are found to have vitamin D deficiency their GP will be informed in order to offer advice and/or treatment. We do not expect there to be any disadvantage from taking part. Participants may experience some redness of the skin for a short while after their sunburn threshold has been tested. There may be slight discomfort and bruising following the blood sample.

Where is the study run from?
Salford Royal NHS Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
November 2014 to October 2017

Who is funding the study?
European Seventh Framework Programme (Belgium)

Who is the main contact?
Mrs Joanne Osman

Contact information

Type(s)
Scientific

Contact name
Mrs Joanne Osman

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17553

Study information

Scientific Title
An experimental photodermatology study to examine the ability of limited skin areas to produce vitamin D

Study objectives
The aim of this study is to determine if exposure of more limited areas of skin to simulated sunlight can produce a sufficient rise in vitamin D levels to avoid deficiency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Manchester Research Ethics Committee, 14/10/2014, ref: 14335.

Study design

Non-randomised; Interventional; Design type: Not specified

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Dermatology; Subtopic: Skin (all Subtopics); Disease: Dermatology

Interventions
The intervention is solar-simulated ultraviolet radiation. A dose of 1.3 SED (standard erythema dose) is given three times a week for 6 weeks. There is no control arm. Blood samples are taken at the start of each week, before the first exposure, and one 3 days after the final exposure. Follow-up will then continue with blood samples after a further 2, 4 and 6 weeks. Total duration for treatment and follow-up = 12 weeks.

Intervention Type
Other

Primary outcome measure
The primary outcome measure is serum 25-hydroxyvitamin D (25(OH)D) concentration which is measured at baseline, then weekly up to 6 weeks. Further samples to be taken at weeks 8, 10 and 12. Serum 25(OH)D is measured by liquid chromatography tandem mass spectrophotometry (LC-MS/MS).

Secondary outcome measures
N/A

Overall study start date
01/11/2014

Completion date
31/10/2017

Eligibility

Key inclusion criteria

1. Healthy, ambulant, male and female adults aged 20-60 years
2. White Caucasian (sun-reactive skin type I-IV)
3. Willing and capable of participating to the extent and degree required by the protocol

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 60; UK Sample Size: 60

Key exclusion criteria
1. Sunbathing or sunbed use in the last 3 months
2. Taking photoactive medication
3. Taking vitamin D, fish oil or calcium supplements
4. History of skin cancer or photosensitivity disorder
5. Pregnancy/lactation

Date of first enrolment
01/11/2014

Date of final enrolment
31/10/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal NHS Foundation Trust
Photobiology Unit
Salford Royal Foundation Hospital
Stott Lane
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M6 8HD

Sponsor information

Organisation
University of Manchester

Sponsor details
Oxford Road
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M13 9PL

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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