

# Limited skin areas and vitamin D

<b>Submission date</b> 04/02/2015	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 04/02/2015	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 08/02/2015	<b>Condition category</b> Skin and Connective Tissue Diseases	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 through 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

Salford Royal NHS Foundation Trust

Photobiology Unit

Salford Royal Foundation Hospital

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Salford

Greater Manchester

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## Additional identifiers

### Protocol serial number

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

### Study type(s)

## Treatment

### 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(s)

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).

### Key secondary outcome(s)

N/A

### 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

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### 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**

United Kingdom

England

**Study participating centre**

**Salford Royal NHS Foundation Trust**

Photobiology Unit

Salford Royal Foundation Hospital

Stott Lane

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## Sponsor information

**Organisation**

University of Manchester

**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****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration