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Hands and face exposure for vitamin D productio

Submission date	Recruitment status	[_] Prospectively registered
10/12/2015	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
10/12/2015	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/05/2021	Skin and Connective Tissue Diseases	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Vitamin D is essential for good health, because it helps our bodies to absorb calcium from the diet. There is a lot of evidence that having enough vitamin D can help prevent against many diseases, such as heart disease, bone diseases and cancer. Although vitamins generally come from the diet, in the case of vitamin D, the majority of people actually get most of it from sunlight. National guidance on requirements for vitamin D assumes 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 only hands and face can produce a sufficient rise in vitamin D levels to avoid deficiency.

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

What does the study involve?
All participants undergo a six week course of treatment, in which they are exposed to simulated sunlight (ultraviolet light) wearing clothes that expose only hands and face. Blood samples are taken at the start of the study, and then once a week so that the amount of vitamin D can be measured.

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. No notable risks are anticipated, however 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 2015 to October 2016

Who is funding the study?
The British Skin Foundation (UK)

Who is the main contact?
1. Dr Mark Farrar (scientific)
2. Mrs Joanne Osman (public)

Contact information

Type(s)
Scientific

Contact name
Dr Mark Farrar

ORCID ID
http://orcid.org/0000-0001-8602-7279

Contact details
Photobiology Unit
Salford Royal NHS Foundation Trust
Hope Hospital
Stott Lane
Salford
Manchester
United Kingdom
M13 9PL

Type(s)
Public

Contact name
Mrs Joanne Osman

Contact details
Photobiology Unit
Salford Royal NHS Foundation Trust
Hope Hospital
Stott Lane
Salford
Manchester
United Kingdom
M6 8HD

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
19889

Study information

Scientific Title
An experimental photodermatology study examining the impact of hands and face exposure on cutaneous vitamin D production

Study objectives
The aim of this study is to examine the change in vitamin D levels of white Caucasian adults during a course of simulated summer sunlight exposures to the hands and face.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Manchester Research Ethics Committee, 22/10/2015, ref: 15440

Study design
Non-randomised; Interventional; Design type: Prevention, Treatment

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 the contact details below to request a patient information sheet

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

Interventions
All participants undergo the intervention involving solar-simulated ultraviolet radiation. A dose of 1.3 SED (standard erythema dose) is given three times a week for 6 weeks. Blood samples are taken at the start of each week, before the first exposure, and one 3 days after the final exposure. Total duration for treatment and follow-up is 6 weeks.

Intervention Type

Other

Primary outcome measure
Serum 25-hydroxyvitamin D (25(OH)D) concentration is measured using liquid chromatography tandem mass spectrophotometry (LC-MS/MS) at baseline and then weekly for up to 6 weeks.

Secondary outcome measures
N/A

Overall study start date
20/04/2015

Completion date
25/10/2016

Eligibility

Key inclusion criteria
1. Aged 20--60 years
2. Ambulant
3. Healthy
4. White Caucasian (sun-reactive skin type I--IV)
5. 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: 40; UK Sample Size: 40

Total final enrolment
44

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

Date of first enrolment
23/11/2015

Date of final enrolment

31/03/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal NHS Foundation Trust
Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
University of Manchester

Sponsor details
Oxford Road
Manchester
England
United Kingdom
M13 9PL

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type
Charity

Funder Name
British Skin Foundation

Alternative Name(s)
BSF

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Primary outcome data will be published once data have been validated and analysed.

Intention to publish date
31/12/2021

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Data sharing statement to be made available at a later date