ISRCTN72674753 https://doi.org/10.1186/ISRCTN72674753

Age-related ability to synthesise vitamin D

Submission date
13/08/2018

Recruitment status
No longer recruiting

Registration date
05/09/2018

Overall study status
Completed

Last Edited
09/09/2024

Condition category
Nutritional, Metabolic, Endocrine

[X] Prospectively registered

[X] Protocol

[X] Statistical analysis plan

[X] Results

[_] Individual participant data

Plain English summary of protocol

Background and study aims
We get most of our vitamin D through exposure to ultraviolet (UV) in sunlight and a small amount from our diet. When skin exposed to sunlight, a molecule called 7-DHC is converted to vitamin D which then enters the bloodstream. The aim of this study is to see if there is a difference between young and older adults in how much Vitamin D their skin is able to produce in response to sunlight.

Who can participate?
Healthy White Caucasian volunteers in two age groups, young (18-40 years) and aged (65-89 years)

What does the study involve?
Volunteers receive a single UV exposure, equivalent to 15 minutes of sunlight exposure in Manchester at midday in June. Skin area exposed reflects casual summer clothing (T shirt and shorts) with lower legs, arms, hands, neck and face exposed. A 10 x 10cm square is cut out of the shorts to allow exposure of an upper buttock area for a skin sample. This work is done between November and February when there is low UV and people have the lowest vitamin D levels. Blood samples are taken before UV exposure and 24 hours and 1 week after UV exposure. Skin samples from the previously protected upper buttock are taken from an unexposed area of skin and from the exposed area of skin immediately after UV exposure. Further samples are taken from the exposed area of skin at 24 hours after UV exposure. Skin and blood samples are tested for vitamin D and related molecules.

What are the possible benefits and risks of participating?
The findings will address a significant knowledge gap - whether the ability to synthesise Vitamin D in skin changes with age. Participants will be informed not to expect individual benefit from participation in the study. Some discomfort may be felt when taking blood and skin samples.

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?
October 2017 to September 2021

Who is funding the study?
Biotechnology and Biological Sciences Research Council (UK)

Who is the main contact?
Professor Lesley Rhodes, lesley.e.rhodes@manchester.ac.uk

Contact information

Type(s)
Scientific

Contact name
Mrs Lesley Rhodes

Contact details
Photobiology Unit
Dermatology Centre
Salford Royal Hospital
Stott Lane
Salford
United Kingdom
M6 8HD
+44 (0)161 206 1150
lesley.e.rhodes@manchester.ac.uk

Type(s)
Public

Contact name
Prof Lesley Rhodes

Contact details
Photobiology Unit
Dermatology Centre
Salford Royal Hospital
Stott Lane
Salford
United Kingdom
M6 8HD
+44 (0)161 206 1150
lesley.e.rhodes@manchester.ac.uk

Type(s)
Scientific

Contact name
Ms Octavia Borecka

ORCID ID
http://orcid.org/0000-0003-4446-9989

Contact details
-
Manchester
United Kingdom
-
-
octavia.borecka@gmail.com

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
235670

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
36225

Study information

Scientific Title
Age-related ability to synthesise vitamin D in the skin on exposure to sunlight

Acronym
AGE_D

Study objectives
Do the skin levels of 7-dehydrocholesterol (DHC) differ in skin of younger and older adults when assessed under carefully controlled protocols, and is the ability of skin to synthesise Vitamin D following ultraviolet radiation exposure, under conditions similar to natural sunlight, different in younger and older adults?

Ethics approval required
Old ethics approval format

Ethics approval(s)
North West - Greater Manchester West Research Ethics Committee, 25/07/2018, ref: 18NW0493

Study design
Non-randomised; Interventional; Design type: Clinical Laboratory Study

Primary study design
Interventional

Secondary study design

Non randomised study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Vitamin D deficiency

Interventions
This is a trial of low-level UVR exposures in a comparative study of human volunteers in 2 age groups, young (18-40 years) and aged (65-89 years). Volunteers will be matched for other attributes including skin type and UV dose administered. Biopsy and blood sampling procedures will be identical. All visits and procedures will be undertaken in the Photobiology Unit, Salford Royal NHS Foundation Trust. Volunteers will receive a single UV exposure, equivalent to 15 minutes of sunlight exposure in Manchester at midday in June. Skin area exposed will reflect casual summer clothing (T shirt and shorts) with lower legs, arms, hands, neck and face exposed (~35% skin surface area). A 10 x 10cm square will be cut out of the short to allow exposure of an upper buttock area for post-UV biopsy. This work will be done between November and February when there is negligible ambient UV and subjects are at their lowest vitamin D status.

Blood samples will be taken pre-UV, and at 24 hours and 1 week post-UV. Skin biopsies from previously protected upper buttock will be taken from an unexposed area of skin and from the exposed area of skin immediately post-UV exposure. Further biopsies will be taken from the exposed area of skin at 24 hours post-UV. Skin samples will be analysed for 7-DHC, pre-vitamin D and vitamin D. Skin biopsy samples will undergo extraction, chromatographic separation, and quantification using tandem mass spectrometry to measure epidermal and dermal content of 7-DHC, pre-vitamin D and related molecules; similar techniques will provide for 25(OH)D analysis of blood samples.

Volunteers will complete a daily diet diary for 1 week and lifestyle questionnaire, as used in previous studies by our group, to assess their dietary sources of vitamin D and general daylight exposure behaviour. Outcomes can be set in context of data from our existing studies of large numbers of younger and older adults showing annual cycles in vitamin D status. Findings will address a significant knowledge gap - whether the ability to synthesise Vitamin D in human skin changes with age.

Intervention Type
Other

Primary outcome measure
Skin level of 7-DHC measured by tandem mass spectrometry at baseline and 24 hours post-UVR intervention

Secondary outcome measures

1. Skin level of pre-vitamin D and vitamin D measured by tandem mass spectrometry at baseline and 24 hours post-UVR intervention
2. Serum 25-hydroxyvitamin D measured by tandem mass spectrometry at baseline and 1 week post-UVR intervention
3. Daily dietary vitamin D intake assessed by diet diary over 1 week

Overall study start date
01/10/2017

Completion date
30/09/2021

Eligibility

Key inclusion criteria
1. Healthy, ambulant human volunteers
2. Male and female
3. Aged 18-40 or 65-89 years
4. White Caucasian (sun-reactive skin types I-III)

Participant type(s)
Healthy volunteer

Age group
Mixed

Lower age limit
18 Years

Upper age limit
89 Years

Sex
Both

Target number of participants
Planned Sample Size: 24; UK Sample Size: 24

Total final enrolment
25

Key exclusion criteria
1. History of photosensitivity disorder or skin cancer
2. Taking photoactive or bone active therapies
3. Sunbathing/sunny holiday/sunbed use in past 3 months
4. Taking vitamin D doses > 200 IU (5 µg)
5. Taking anti-coagulation medicines including Aspirin, Clopidogrel and Warfarin or Propranolol

Date of first enrolment

01/10/2018

Date of final enrolment
30/03/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Salford Royal Hospital
Photobiology Unit
Stott Lane
Salford
United Kingdom
M6 8HD

Sponsor information

Organisation
The University of Manchester

Sponsor details
Faculty of Biology, Medicine and Health
1.21a Simon Building
Manchester
England
United Kingdom
M13 9PL
+44 (0)161 275 5436
FBMHethics@manchester.ac.uk

Sponsor type
University/education

ROR
https://ror.org/027m9bs27

Funder(s)

Funder type

Research council

Funder Name
Biotechnology and Biological Sciences Research Council; Grant Codes: BB/M011208/1

Alternative Name(s)
UKRI - Biotechnology And Biological Sciences Research Council, BBSRC UK, BBSRC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Outcomes will be communicated to the research community through publication in high-impact open access general and specialist journals within one year of the study end-date. Findings will be communicated to wider audiences via relevant charities and societies promoting research and public education, including the BBSRC (funder). Communication of findings to UK government bodies formulating health policy and guidance relating to vitamin D acquisition will be expedited through the investigatory team's several active roles on relevant public health and medical committees.

Intention to publish date
30/09/2024

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from the Principal Investigator Prof. Lesley Rhodes (Lesley.e.rhodes@manchester.ac.uk). Data will be available following primary publication of study results. Consent for data sharing will be obtained from participants and all shared data will be fully anonymised.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version v1	25/07/2018	05/09/2018	No	Yes
Protocol file		23/03/2018	05/09/2018	No	No

Other publications	analysis of behaviours influencing vitamin D intake	24/03/2021	13/08/2021	Yes	No
Statistical Analysis Plan			18/07/2023	No	No
Results article		12/04/2024	09/09/2024	Yes	No