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# 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


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Scientific

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# Additional identifiers

**Integrated Research Application System (IRAS)**
235670

**Protocol serial number**
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

**Primary study design**
Interventional

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

**Study type(s)**
Other

**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(s)
Skin level of 7-DHC measured by tandem mass spectrometry at baseline and 24 hours post-UVR intervention

### Key secondary outcome(s)
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

### 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

**Healthy volunteers allowed**
No

**Age group**
Mixed

**Lower age limit**
18 Years

**Upper age limit**
89 Years

**Sex**
All

**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**
United Kingdom

England

**Study participating centre**
**Salford Royal Hospital**
Photobiology Unit
Stott Lane
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# Sponsor information

**Organisation**
The University of Manchester

**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, Agricultural and Food Research Council, Biotechnology & Biological Sciences Research Council, BBSRC, BBSRC UK, AFRC

**Funding Body Type**
Government organisation

**Funding Body Subtype**
National government

**Location**
United Kingdom

# Results and Publications

**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? |
|---|---|---|---|---|---|
| Results article | | 12/04/2024 | 09/09/2024 | Yes | No |
| Other publications | analysis of behaviours influencing vitamin D intake | 24/03/2021 | 13/08/2021 | Yes | No |
| Participant information sheet | version v1 | 25/07/2018 | 05/09/2018 | No | Yes |
| Protocol file | | 23/03/2018 | 05/09/2018 | No | No |
| Statistical Analysis Plan | | | 18/07/2023 | No | No |