

# Vitamin D supplementation and immune regulation study

<b>Submission date</b> 20/04/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results <input type="checkbox"/> Individual participant data
<b>Registration date</b> 22/05/2020	<b>Overall study status</b> Completed	
<b>Last Edited</b> 16/07/2021	<b>Condition category</b> Nutritional, Metabolic, Endocrine	

## Plain English summary of protocol

### Background and study aims

Ultraviolet B (UVB) light, which is found in summer sunlight, is known to have important effects on the human body including making vitamin D. It may also be involved in balancing the immune system. The northern location of Aberdeen means that making vitamin D in the winter is not possible. It has been suggested that this may be one of the reasons why certain diseases, like psoriasis and multiple sclerosis, occur more commonly in the north. There could be other reasons, which is why the researchers want to test the effect of vitamin D on immune system balance. Their previous research showed that giving artificial UVB in winter increased both vitamin D status and 'regulatory' white blood cells that are important in preventing these diseases. This study will compare the effects of Vitamin D with placebo (dummy supplement) on the normal balance in immune cells. This is part of a student project in which the student is fully supervised.

### Who can participate?

Healthy adults over the age of 18 years living in North East Scotland

### What does the study involve?

Potential participants will be asked to visit the Heath Sciences Building (on the Foresterhill site) for a total of five visits. At the first visit, they will have the chance to ask any questions they may have. If they still want to go ahead with the study after asking questions, they will be asked to sign a consent form. Then the researchers will measure their height and weight and they will be asked to fill in questionnaires about their dietary intake of vitamin-D rich foods and seasonal sunlight behaviours (including the average time spent outside each day and body surface exposed for each season). Participants are randomly allocated to take daily oral vitamin D or placebo capsules for 10 months.

There will be four more visits after the first one over a 10-month period at 4 weeks, 12 weeks, 25 weeks, and 43 weeks after the first visit.

The following measurements will happen at each visit. They will be asked to attend four visits in total for a blood sample (45 ml or 9 teaspoons). Participants will be asked not to eat anything from midnight before each visit. The researchers will use a special camera to measure the colour of the skin on their face and arm. It does not take a photograph of their skin but gives measurements of skin colour. Skin colour changes when exposed to the type of sunlight that

makes vitamin D. After each visit, participants will also be asked to wear a small badge on their outside clothing for one week. The badge will measure the levels of UV-B light they receive from the sun when outdoors. The researchers will also ask them to record their sun exposure habits on the days they wear the badges. Participants are asked to not take any vitamin D or fish oil supplements before or during the study and not to use a tanning bed. If they go abroad for a sunny holiday or actively sunbathe in the UK, the researchers will make a note of this information to help with interpretation of the results. Otherwise participants are asked to carry on as normal and continue to take any regular medication that will not affect the study. They would discontinue the study if they become pregnant.

What are the possible benefits and risks of participating?

There is no clear personal benefit to participants from taking part in the study. Regarding risks, there may be slight discomfort during taking the blood sample. All blood samples will be taken by only qualified phlebotomists. Vitamin D supplements are within recommended nutritional guidelines and are therefore quite safe. The placebo contains a non-reactive compound. Neither should cause any side effects.

Where is the study run from?

University of Aberdeen (UK)

When is the study starting and how long is it expected to run for?

November 2014 to January 2016

Who is funding the study?

1. RANK organisation
2. Pathways to a Healthy Life Studentship
3. University of Aberdeen Development Fund
4. NHS Endowment Fund

Who is the main contact?

1. Dr Frank Thies  
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2. Dr Wakuyambo Maboshe  
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## Contact information

### Type(s)

Public

### Contact name

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### Contact details

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Scientific

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number****ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

## Study information

**Scientific Title**

The D-SIRe2 study: a randomised placebo-controlled trial assessing the short-term (12 weeks) and long-term (43 weeks) effects of low-dose vitamin D3 Supplementation on markers of Immune system Regulation in healthy volunteers in the northeast of Scotland.

**Acronym**

D-SIRe2

**Study objectives**

Low-dose vitamin D3 will cause greater changes in proportions of Tregs and other immune markers in healthy adults living in Aberdeenshire more than healthy adults taking a placebo capsule.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Approved 22/01/2015, University of Aberdeen College of Life Sciences and Medicine Ethics Review Board (University of Aberdeen, King's College, Aberdeen, AB24 3FX, UK; +44 (0)1224 438395; justin.williams@abdn.ac.uk), ref: CERB/2014/12/1153

### **Study design**

Single-centre two-arm 43-week randomised placebo-controlled intervention

### **Primary study design**

Interventional

### **Secondary study design**

Randomised controlled trial

### **Study setting(s)**

Other

### **Study type(s)**

Other

### **Participant information sheet**

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

### **Health condition(s) or problem(s) studied**

Nutritional immunology

### **Interventions**

Participants were randomised using a web-based system managed by the Health Service Research Unit to receive daily oral supplementation with 400 IU vitamin D3 or placebo capsules for a period of 43 weeks (10 months).

There will be four more visits after the first one over a 10-month period at 4 weeks, 12 weeks, 25 weeks, and 43 weeks after the first visit.

### **Intervention Type**

Supplement

### **Primary outcome measure**

The number of circulating Treg cells as a proportion of peripheral blood mononuclear cells (PBMCs) measured by flow cytometry following venous blood collection at baseline, weeks 4, 12, 25 and 43

## Secondary outcome measures

Measured at baseline, weeks 4, 12, 25 and 43:

1. Serum 25(OH)D measured using tandem mass spectrometry as a response to vitamin D supplementation
2. Cytokine secretion (IL-10, and interferon-gamma) measured by ELISA
3. T cell proliferation in response to T cell stimulation measured by tritiated thymidine incorporation

## Overall study start date

10/11/2014

## Completion date

29/01/2016

## Eligibility

### Key inclusion criteria

1. Healthy individuals
2. Male or female
3. Aged 18 years or over
4. People taking  $\leq 200$  IU/day vitamin D at screening but stopped taking the supplements during the study

### Participant type(s)

Healthy volunteer

### Age group

Adult

### Lower age limit

18 Years

### Sex

Both

### Target number of participants

60

### Total final enrolment

62

### Key exclusion criteria

1. Pregnant or lactating
2. Receiving immunosuppressive or anti-inflammatory drug therapy
3. Taking vitamin D supplements ( $> 100$  IU or  $2.5 \mu\text{g/day}$ )
3. Immune-mediated disorders such as rheumatoid arthritis, multiple sclerosis, asthma, hay fever, lupus or eczema; kidney disease; cancer or other serious immune compromising conditions
4. Planned long-term ( $> 1$  month) holidays abroad to sunny destinations

### Date of first enrolment

06/02/2015

**Date of final enrolment**

03/04/2015

## **Locations**

**Countries of recruitment**

Scotland

United Kingdom

**Study participating centre**

**University of Aberdeen**

Health Sciences Building

Foresterhill

Aberdeen

United Kingdom

AB25 2ZN

## **Sponsor information**

**Organisation**

University of Aberdeen

**Sponsor details**

Research and Development Office

Foresterhill House Annexe

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researchgovernance@abdn.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.abdn.ac.uk/>

**ROR**

<https://ror.org/016476m91>

# Funder(s)

## Funder type

Other

## Funder Name

RANK Nutrition Prize Studentship

## Funder Name

Pathways to a Healthy Life Theme

## Funder Name

The University Development Fund

## Funder Name

NHS Endowment Fund

# Results and Publications

## Publication and dissemination plan

The study protocol will be made available and it is not already published or available online. The findings of the trial will be made publicly available through publication in a peer-reviewed journal including an accurate and transparent account of the trial.

## Intention to publish date

01/10/2020

## Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available. A data sharing policy was not established at the time of study set up in 2014 and the ethical approval was not inclusive of secondary use, with access to data only approved for researchers involved in the analysis. For this reason and without a pre-existing data sharing plan, there are currently insufficient processes, tools, and governance mechanism to process access requests for secure data sharing.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>		28/06/2021	16/07/2021	Yes	No

