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Vitamin D supplementation and immune regulation study

Submission date
20/04/2020

Recruitment status
No longer recruiting

Registration date
22/05/2020

Overall study status
Completed

Last Edited
16/07/2021

Condition category
Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

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?
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Public

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
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

Study type(s)
Other

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(s)
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

Key secondary outcome(s))
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

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 ≤ 200 IU/day vitamin D at screening but stopped taking the supplements during the study

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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 µg/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
United Kingdom

Scotland

Study participating centre
University of Aberdeen
Health Sciences Building
Foresterhill

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Sponsor information

Organisation
University of Aberdeen

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

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?
Results article		28/06/2021	16/07/2021	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes