

Vitamin D effects on Cardiovascular disease Risk

Submission date 01/05/2008	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 07/08/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 06/09/2013	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Background and study aims:

Vitamin D is an unusual vitamin because for most people sunlight, not food, is the major source of the vitamin. It is well known that vitamin D is important for bones but recent research has linked vitamin D with other health outcomes, including heart health. This could have implications in the UK, because between the months of October and April, there is a lower strength of the type of sunlight we need to make vitamin D in the skin.

This study investigated whether giving daily vitamin D supplements could help reduce heart disease risk in postmenopausal women over one year.

Who can participate?

Healthy postmenopausal women aged between 60-70 years living in the Aberdeen area.

What does the study involve?

Participants were randomly allocated to receive either high or low dose vitamin D or placebo (dummy vitamin). Participants were asked to take one capsule every day with breakfast for 12 months. At each visit, study investigators collected a small blood sample to assess vitamin D status and a range of factors related to heart health. Participants were also asked to complete questionnaires on physical activity and habitual diet. Questions relating to general health, chronic pain, sun exposure and holidays abroad were also asked. After each visit, participants were asked to wear a small polysulphone film badge on the lapel on their outside coat or jacket for one week to measure sunlight exposure. At the beginning and end of the study, the participants bone mineral density and body composition were measured.

What are the possible benefits and risks of participating?

There are no direct benefits other than the information that participants will receive from their GP about their bone health after the bone scan. There are minor risks associated with blood collection which include excessive bleeding, fainting or feeling light headed, haematoma (blood collecting under the skin), and infection (a slight risk any time the skin is broken). There is a minor radiation exposure from the bone scan (similar to background radiation in Aberdeen).

Where is the study run from?

University of Aberdeen, UK

When is the study starting and how long is it expected to run for?
The study started in September 2008 and ended in 2010

Who is funding the study?
Department of Health, UK
National Osteoporosis Society, UK

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
pRGF/075/08

Study information

Scientific Title
Effect of one year vitamin D intervention on risk of cardiovascular disease: a randomised controlled trial at 57°N

Acronym
VICtORy

Study objectives

1. Does supplementing the diet with high or low doses of oral vitamin D3 (25 µg [dietary recommendations in the United States of America] or 10 µg [United Kingdom reference nutrient intake for over 65 year olds, or individuals at risk of vitamin D deficiency] daily respectively) reduce cardiovascular disease (CVD) risk markers and insulin sensitivity?

2. Does supplementing the diet with high or low doses of oral vitamin D3 (25 µg or 10 µg daily respectively) raise vitamin D status equally in overweight and lean individuals, and does adipose tissue distribution influence vitamin D status?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval has been sought from the National Health Service Ethics Committee (NHS REC): Grampian Local Research Ethics Committee. Submitted on 22nd April 2008 and a decision will be made on the 8th May 2008 (ref: 08/S0802/73).

Study design

Randomised double blind placebo controlled trial - single centre

Primary study design

Interventional

Study type(s)

Quality of life

Health condition(s) or problem(s) studied

Vitamin D status, CVD risk, insulin sensitivity

Interventions

This is a randomised double blind placebo controlled trial with supplementation starting in January 2009, aiming to assess whether dietary supplementation with oral vitamin D3 (10 µg or 25 µg) daily for 12 months reduces cardiovascular risk and insulin sensitivity. This could influence policy making decisions regarding dietary guidelines and in particular help set reference nutrient intakes using non-bone health outcomes in the over 60s. As there is concern that for any given intake of dietary vitamin D the circulating 25(OH)D does not increase as expected in overweight individuals, we will determine whether distribution of adipose tissue influences the effectiveness of the intervention, which will help to identify 'at risk' individuals.

Study visits will be held at two monthly intervals for 12 months (eight visits in total). Participants will be randomised to receive placebo, 10 µg or 25 µg oral vitamin D3. We will use minimisation criteria for vitamin D receptor (VDR) genotype, apolipoprotein E (ApoE) genotype (which is known in our study cohort), overweight (greater than or less than 25 kg/m²) and smoking, so that the groups will be equally matched.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Oral vitamin D3 supplementation

Primary outcome(s)

All primary and secondary outcomes will be measured at each study visit, i.e. at baseline, 2-, 4-, 6-, 8-, 10- and 12-month visits. Adipose tissue distribution will be measured at pre- and post-supplementation visits only.

1. Blood samples will be analysed for total cholesterol, high density lipoprotein (HDL)-cholesterol, low density lipoprotein (LDL)-cholesterol, triglycerides, apolipoprotein A1, apolipoprotein B100, fasted serum glucose, non-esterified fatty acids, insulin, glucose, intercellular adhesion molecule-1 (ICAM-1), interleukin-6 (IL-6), high sensitivity C-Reactive Protein (hsCRP), 25(OH)D, and routine hypercalcaemia
2. Three blood pressure measurements will be taken at each visit (first discarded and mean result of the following two will be used using an OMRON705CP sphygmomanometer accredited by the British Heart Foundation)
3. Fasted urine samples will be collected in a willing sub-group of women and stored for future analysis of bone turnover markers
4. Adipose tissue distribution will be measured pre- and post-supplementation by dual energy x-ray absorptiometry (iDXA) full body scan

Key secondary outcome(s)

All primary and secondary outcomes will be measured at each study visit, i.e. at baseline, 2-, 4-, 6-, 8-, 10- and 12-month visits. Adipose tissue distribution will be measured at pre- and post-supplementation visits only.

1. Sunlight exposure will be assessed by a ultraviolet (UV) polysulphone film badge (3 cm in size) worn on the lapel of the outside coat or jacket for 7 days, which will monitor the amount of sunlight participants are getting in the following week
2. Diet will be assessed using a validated food frequency questionnaire to be completed at home
3. Physical activity level will be assessed using a validated physical activity questionnaire (which has already been used in other cohorts of post-menopausal women) to be completed at home
4. Grip strength will be assessed in a willing sub-group of women (as muscle strength may change depending on vitamin D status) using a grip strength dynamometer. The average of three readings will be taken.
5. Incidence of chronic pain will be assessed using a pain mannikin questionnaire

Completion date

31/01/2010

Eligibility

Key inclusion criteria

Women from a previous screening study (Aberdeen Prospective Osteoporosis Screening Study - APOSS) aged between 60 and 70 years.

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Senior

Sex

Female

Key exclusion criteria

Participants will be excluded if they:

1. Have been diagnosed with CVD
2. Have been diagnosed with diabetes
3. Have been diagnosed with asthma
4. Have high blood pressure (i.e. systolic blood pressure greater than 160 mmHg or diastolic pressure greater than 99 mmHg)
5. Suffer from chronic gastro-intestinal disease associated with malabsorption (e.g. coeliac disease, crohn's disease)
6. Are taking any medication regularly which might affect outcome measures such as hypotensive, hypolipemic, anti-inflammatory, or oral corticosteroid users

Date of first enrolment

01/10/2008

Date of final enrolment

31/01/2010

Locations**Countries of recruitment**

United Kingdom

Scotland

Study participating centre

Osteoporosis Research Unit

Aberdeen

United Kingdom

AB25 2ZD

Sponsor information**Organisation**

University of Aberdeen (UK)

ROR

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

Funder(s)

Funder type
Government

Funder Name
Food Standards Agency (UK) (ref: N05R0015)

Alternative Name(s)
The Food Standards Agency, FSA

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2012		Yes	No
Results article	results	01/10/2013		Yes	No
Results article	results	01/01/2014		Yes	No