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VItamin D effects on CardiOvascular disease Risk

Submission date	Recruitment status	[X] Prospectively registered
01/05/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
07/08/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/09/2013	Nutritional, Metabolic, Endocrine	

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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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/m^2) 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 measure
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

Secondary outcome measures
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 dynanometer. The average of three readings will be taken.
5. Incidence of chronic pain will be assessed using a pain mannikin questionnaire

Overall study start date
01/10/2008

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

Age group
Senior

Sex
Female

Target number of participants
300 (100 participants for each intervention arm: high vitamin D, low vitamin D, and placebo)

Key exclusion criteria
Patricipants 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
Scotland

United Kingdom

Study participating centre
Osteoporosis Research Unit
Aberdeen

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Sponsor information

Organisation
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University/education

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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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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