ISRCTN96210443 https://doi.org/10.1186/ISRCTN96210443

15-month longitudinal study of dietary and sunlight influences on vitamin D status in a well-characterised population of postmenopausal women at 57°N

Submission date
04/09/2007

Recruitment status
No longer recruiting

Registration date
16/10/2007

Overall study status
Completed

Last Edited
01/08/2013

Condition category
Musculoskeletal Diseases

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

Plain English summary of protocol

Background and study aims
At present the UK government only recommends a level of dietary vitamin D for people aged over 65 or people who may be at risk of vitamin D deficiency. This could include people that rarely spend time outside or cover up if they do go outside. However, for normal adults, it is assumed that all the necessary vitamin D will come from sunshine. In the UK we do not have enough sunlight of the correct wavelength in the winter months to make vitamin D in our skin. Therefore, because there are few foods that naturally contain vitamin D, our vitamin D stores tend to decrease during winter. We would like to investigate what happens to vitamin D levels throughout the year in the North of Scotland.
The aim of this project was to measure vitamin D status in healthy postmenopausal women aged <65 years, over at least one year; to assess vitamin D deficiency at different seasons; and to assess the relative contributions of sunlight exposure and diet to vitamin D status at each season.

Who can participate?
Healthy postmenopausal women aged between 55 -65 years living in the Aberdeen area.

What does the study involve?
There are no treatments involved in this study. Once every three months for 15 months (five visits in total) starting in Spring 2006 participants visit our unit for a fasting blood sample to assess vitamin D status. Some of this sample will be stored for possible future analysis of diet or bone markers. We will use a handheld colorimeter (a device similar to a camera) to measure skin colour, which may gradually change over the period of the study depending on the amount of sunlight. We will also measure grip strength by asking the participant to squeeze a small metal bar for a few seconds, as muscle strength may change depending on vitamin D status.
After each visit participants will be asked to complete a food questionnaire or food diary for 7 days along with a physical activity questionnaire. They will also be asked to wear a small badge on the lapel of the outside coat or jacket for 7 days which will monitor the amount of sunlight

they will be getting in a week. They will be asked to complete a sunlight exposure and falls diary. A subset of women will be asked if they would also be prepared to wear an accelerometer for 7 days after each visit. An accelerometer is a non-invasive device the size of a pager that is worn on the waist and measures body movement.
During the course of the study the participant will have the opportunity to have two bone scans, one in the autumn and one the following spring. After the second scan the results of both scans will be reported to your GP.

What are the possible benefits and risks of participating?
There are no direct benefits, besides the information they will receive from their GP about their bone health after the bone scan. There are no side effects except those associated with having a blood sample taken. There is minor radiation exposure with the bone scan (similar to background radiation in Aberdeen).

Where is the study run from?
The University of Aberdeen.

When is study starting and how long is it expected to run for?
The study started in March 2006 and has ended. It lasted for 15 months and participants were asked to attend an additional one-off visit in Spring 2008, to allow comparison of vitamin D status across three spring periods (when vitamin D status is likely to be at its lowest).

Who is funding the study?
The study was funded by the UK Food Standards Agency.

Who is the main contact?
Dr Helen Macdonald
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
Food Standards Agency ref no: N05062

Study information

Scientific Title

Acronym
ANSaVID (Aberdeen Nutrition Sunlight and VItamin D study)

Study objectives
To establish whether diet and previous summer's sunlight exposure maintain vitamin D levels at northerly latitudes of the United Kingdom (UK) and determine how much dietary vitamin D is required (if any).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approval received from the National Health Service Research Ethics Committee (NHS REC): Grampian Local Research Ethics Committee on the 13th January 2006 (ref: 05/S0802/149).

Study design
Observational longitudinal study - single centre

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Not specified

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Low bone mass/risk of osteoporosis

Interventions

This is a 15-month observational study starting in March 2006 aiming to assess how diet and sunlight exposure influence vitamin D status for each three-monthly season. There will be five visits in total.

All women will complete food diaries, sunlight exposure and falls diaries, physical activity questionnaires, and have grip strength assessed at three-month intervals (five visits in total) and wear sunlight exposure badges for one week every three months. There will also be a quantitative measure of sunlight exposure using a hand held spectrophotometer/chromometer which measures skin colouration. At each visit the women will be asked if they will provide a blood sample for measurement of 25-hydroxy vitamin D (a marker of vitamin D status) and bone turnover markers. All women will be offered two bone mineral density scans: the first in the autumn and the second the following spring.

A subgroup of women (n = 48) will use accelerometers for one week every three months to estimate physical activity in more detail.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Monitor longitudinally the seasonal variation in vitamin D status at a northerly latitude, assessing the individual contributions of sunlight and diet.

All primary and secondary outcomes were measured at each visits, i.e., at Baseline (BL), 3-month, 6-month, 9-month and 12-month visits.

Secondary outcome measures
1. Monitor seasonal variation in physical activity (confounder of vitamin D status)
2. Monitor seasonal variation in:
2.1. Markers of bone turnover (functional marker)
2.2. Falls, muscle strength (functional markers not related to bone health)
3. Determine the relationship between vitamin D status, functional markers (Bone Mineral Density [BMD], bone resorption, muscle strength) with and without adjustment for physical activity level

All primary and secondary outcomes were measured at each visits, i.e., at Baseline (BL), 3-month, 6-month, 9-month and 12-month visits; BMD was measured at 6-month and 9-month visits only.

Overall study start date
01/01/2006

Completion date
31/10/2008

Eligibility

Key inclusion criteria

Women from a previous sceening study (Aberdeen Prospective Osteoporosis Screening Study - APOSS) aged less than 65 years.

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
360

Key exclusion criteria
Participants will be excluded if they:
1. Have chronic gastro-intestinal disease associated with malabsorption
2. Are taking oral corticosteroids
3. Are receiving bisphosphonate therapy (as there is a possibility of interaction with vitamin D metabolism)

Date of first enrolment
01/01/2006

Date of final enrolment
31/10/2008

Locations

Countries of recruitment
Scotland

United Kingdom

Study participating centre
Osteoporosis Research Unit
Aberdeen
United Kingdom
AB25 2ZD

Sponsor information

Organisation

Food Standards Agency (UK)

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Sponsor type
Industry

Website
http://www.food.gov.uk/

ROR
https://ror.org/05p20a626

Funder(s)

Funder type
Industry

Funder Name
Food Standards Agency (UK) (ref: N05062)

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	01/06/2011		Yes	No