

An investigation of the dietary requirements for vitamin D

Submission date
20/12/2007

Recruitment status
No longer recruiting

Prospectively registered

Protocol

Registration date
21/02/2008

Overall study status
Completed

Statistical analysis plan

Results

Last Edited
17/10/2012

Condition category
Nutritional, Metabolic, Endocrine

Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Prof Kevin Cashman

Contact details
Department of Food and Nutritional Sciences
University College Cork
Cork
Ireland
N/A

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N05R0003

Study information

Scientific Title

Dietary requirements for vitamin D: an investigation of the relative significance of dietary intake and sunlight on vitamin D status in young and elderly adults

Study objectives

We hypothesise that additional dietary vitamin D is required to prevent nutritional deficiency during winter in young and elderly adults.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the University of Ulster Research Ethics Committee on the 22nd March 2006 (ref: REC/06/13)

Study design

Double blinded randomised placebo controlled intervention study - multicentre collaboration (University of Ulster and University College Cork)

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Dietary vitamin D intake and status

Interventions

Oral daily supplementation with vitamin D3 of the following doses:

1. Placebo (no treatment)
2. 5 mcg
3. 10 mcg
4. 15 mcg

Supplementation is provided for six months from October to March. There is no additional follow-up. However there is a run-in phase during the preceding summer when participants are asked to keep a diary of sun exposure and activities outdoors. This is assessed in July and August.

Intervention Type

Supplement

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Vitamin D supplementation

Primary outcome measure

1. Serum 25 hydroxyvitamin D concentrations
2. Serum parathyroid hormone concentrations
3. Serum calcium concentrations
4. Dietary calcium and vitamin D intakes (from four-day food diary and food frequency questionnaire)

Secondary outcome measures

1. Bone mineral density (from dual energy x-ray absorptiometry [DXA] scan of spine, hip and whole body)
2. Body composition measurements
3. Immune markers
4. Bone turnover markers

Overall study start date

01/04/2006

Completion date

31/12/2008

Eligibility**Key inclusion criteria**

1. Consenting adult men and women
2. Aged 20 - 85 years
3. In general good health

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

240 from Coleraine and 240 from Cork

Key exclusion criteria

1. Severe medical illness
2. Hypercalcaemia
3. Known intestinal malabsorption syndrome
4. Excessive alcohol use
5. Those who took medications known to interfere with vitamin D metabolism
6. Pregnancy or planning to become pregnant during the six months of the intervention

7. Those taking high dose vitamin D-containing supplements for three months before initiation of study
8. Those who over the six-month course of intervention are planning a winter vacation to a location at which either the altitude or the latitude would be predicted to result in significant cutaneous vitamin D synthesis from solar radiation (e.g., a mountain ski resort or a winter sun coastal resort)

Date of first enrolment

01/04/2006

Date of final enrolment

31/12/2008

Locations

Countries of recruitment

Ireland

Study participating centre

Department of Food and Nutritional Sciences

Cork

Ireland

N/A

Sponsor information

Organisation

Food Standards Agency (UK)

Sponsor details

UK Headquarters

Aviation House

125 Kingsway

London

United Kingdom

WC2B 6NH

Sponsor type

Government

Website

<http://www.food.gov.uk>

ROR

<https://ror.org/05p20a626>

Funder(s)

Funder type

Government

Funder Name

Food Standards Agency (UK) (ref: N05R0003)

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	01/05/2009		Yes	No
Results article	results	01/03/2011		Yes	No
Results article	results	01/08/2012		Yes	No