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An investigation of the dietary requirements for vitamin D

Submission date	Recruitment status	[_] Prospectively registered
20/12/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/02/2008	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
17/10/2012	Nutritional, Metabolic, Endocrine	

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
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)

Key secondary outcome(s))
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

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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

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