ISRCTN40736890 https://doi.org/10.1186/ISRCTN40736890

A dose-response, double-blind, randomised placebo-controlled trial to estimate the dietary requirement for vitamin D in male and female adolescents aged 14-18 years

Submission date
08/05/2014

Recruitment status
No longer recruiting

Registration date
08/05/2014

Overall study status
Completed

Last Edited
23/09/2016

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

16337

Study information

Scientific Title
A dose-response, double-blind, randomised placebo-controlled trial to estimate the dietary requirement for vitamin D in male and female adolescents aged 14-18 years (The ODIN Study)

Acronym
ODIN

Study objectives
No intervention studies have comprehensively investigated the vitamin D requirements of adolescents. The proposed ODIN Study will enable a better understanding of how adolescents respond to vitamin D supplementation (at levels of 10µg and 20µg) and the most effective daily amount that will raise and maintain vitamin D status in adolescents during the winter-time. In addition, investigations into the mechanisms of action with respect to any differences observed across the doses of vitamin D and between the genders of the participants will also provide key information. Mechanisms of action will focus on genetic differences as well as differences in vitamin D metabolising enzymes.

The results obtained from this significant study will not only inform the European Food Standards Agency (EFSA) with respect to their imminent deliberations regarding vitamin D recommendations. The ODIN Study will also inform the UK Department of Healths Scientific Advisory Committee on Nutrition (SACN), the wider scientific community and be a critical resource for key stakeholders (i.e. food industry, government health agencies) to collaborate in determining future public health strategies, thus potentially positively impacting on the health of the population for years to come.

Ethics approval required
Old ethics approval format

Ethics approval(s)
14/WM/0090; First MREC approval date 17/04/2014

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Topic: Primary Care; Subtopic: Not Assigned; Disease: All Diseases

Interventions
Participants will be randomised to receive either 10mcg vitamin D, 20mcg vitamin D or a placebo

Follow Up Length: 5 month(s)

Intervention Type
Supplement

Primary outcome measure
Serum 25-hydroxyvitamin D concentrations; Timepoint(s): End of study (20 weeks after supplementation has begun)

Secondary outcome measures
Not provided at time of registration

Overall study start date
19/05/2014

Completion date
24/10/2014

Eligibility

Key inclusion criteria
1. Male or female
2. Aged between 14 and 18 years
3. In good health
4. Written informed consent from the adolescent (and parent if required)

Participant type(s)
Healthy volunteer

Age group
Child

Lower age limit
14 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 120; UK Sample Size: 120

Key exclusion criteria
1. Currently receiving treatment for medical conditions likely to affect vitamin D metabolism
2. Hypercalcaemia (>2.5mmol/l)
3. Regular use of sunbeds
4. Having a sun holiday one month prior to commencing the trial or plans for a sun holiday within the study period.
5. Use of vitamin supplements containing vitamin D if the prospective participant agrees to stop vitamin D supplementation to join the study, a washout period of 8 weeks prior to commencing the trial would be acceptable.
6. Excessive consumption of alcohol (>14 units per week for females, >21 units per week for males)
7. Smoking >10 cigarettes per day
8. Those following a weight-reducing diet or under dietary restriction (except vegetarianism)
9. Known intolerance/allergy to the constituent ingredients of the daily supplement
10. Clinically significant haematological abnormalities other than mild anaemia (Hb<12.0g/dl)
11. Active malignancy
12. Pregnant or planning a pregnancy during the study period.

Date of first enrolment
19/05/2014

Date of final enrolment
24/10/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
University of Surrey
Guildford
United Kingdom
GU2 7XH

Sponsor information

Organisation
University of Surrey (UK)

Sponsor details
Faculty of Health and Medical Science
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England
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Sponsor type
University/education

ROR
https://ror.org/00ks66431

Funder(s)

Funder type
Government

Funder Name
Seventh Framework Programme (Grant Codes: 613977)

Alternative Name(s)
EC Seventh Framework Programme, European Commission Seventh Framework Programme, EU Seventh Framework Programme, European Union Seventh Framework Programme, FP7

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

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	01/11/2016		Yes	No
HRA research summary			28/06/2023	No	No