

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	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 08/05/2014	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 23/09/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> 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

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 Health's 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 ($>2.5\text{mmol/l}$)
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 ($\text{Hb} < 12.0\text{g/dl}$)
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
Guildford
England
United Kingdom
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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