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# 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

**Protocol serial number**
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

## Study type(s)
Treatment

## 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(s)

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

### Key secondary outcome(s))
Not provided at time of registration

### 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

### Healthy volunteers allowed
No

### Age group
Child

### Lower age limit
14 years

### Upper age limit
18 years

### Sex
All

### 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**
United Kingdom

England

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

# Sponsor information

**Organisation**
University of Surrey (UK)

**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

### 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 |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |