An investigation of the effect of introducing vitamin D2 enriched mushrooms in the diet

Submission date	Recruitment status	Prospectively registered
29/01/2011	No longer recruiting	Protocol
Registration date	Overall study status	Statistical analysis plan
11/04/2011	Completed	Results
Last Edited	Condition category	Individual participant data
11/04/2011	Nutritional, Metabolic, Endocrine	Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Dr Lorraine Brennan

Contact details

UCD Conway Institute Belfield Dublin Ireland D4

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers N/A

Study information

Scientific Title

An investigation of the effect of introducing vitamin D2 enriched mushrooms in the diet: a randomised double-blind placebo-controlled dietary intervention study

Acronym

MMD

Study objectives

To ascertain if daily consumption of vitamin D2 enriched mushrooms can increase vitamin D status in free living healthy adults.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Human Research Ethics Committee in University College Dublin (UCD) approved on the 24th November 2010 (ref: LS-10-152-Brennan-Gibney)

Study design

Randomised double-blind placebo-controlled intervention study

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 the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied

Vitamin D supplementation

Interventions

Participants will be randomised to one of four treatment groups. The four treatment groups are defined as follows:

Group 1: daily vitamin D2 enriched mushrooms

Group 2: daily standard mushrooms

Group 3: daily vitamin D3 capsule (15 µg)

Group 4: daily vitamin D placebo capsule

Total duration of intervention: 4 weeks

Intervention Type

Supplement

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Vitamin D2

Primary outcome measure

Circulating concentration of vitamin D, performed pre- and post- 4-week intervention

Secondary outcome measures

Metabolites relating to glucose and lipid metabolism, performed pre- and post- 4-week intervention

Overall study start date

26/01/2011

Completion date

01/12/2013

Eligibility

Key inclusion criteria

Healthy male and females free-living Caucasians aged 30 - 65 years

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

80

Key exclusion criteria

- 1. Body mass index (BMI) less than 18.0 or 31.0 (kg/m2)
- 2. Any chronic or infectious disease
- 3. Any prescribed medication (contraceptive pills and hormone replacement therapy will be permitted)
- 4. Pregnant or lactating females

Date of first enrolment

26/01/2011

Date of final enrolment

01/12/2013

Locations

Countries of recruitment

Ireland

Study participating centre UCD Conway Institute

Dublin Ireland D4

Sponsor information

Organisation

University College Dublin (UCD) (Ireland)

Sponsor details

Belfield Dublin Ireland D4

Sponsor type

University/education

Website

http://www.ucd.ie/

ROR

https://ror.org/05m7pjf47

Funder(s)

Funder type

Industry

Funder Name

Monaghan Mushrooms (Ireland)

Results and Publications

Publication and dissemination planNot provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summaryNot provided at time of registration