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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 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