

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

<b>Submission date</b> 29/01/2011	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 11/04/2011	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 11/04/2011	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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

**Protocol serial number**  
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

**Study type(s)**

Treatment

**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(s)**

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

**Key secondary outcome(s)**

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

**Completion date**

01/12/2013

## Eligibility

### Key inclusion criteria

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

### Participant type(s)

Patient

### Healthy volunteers allowed

No

### Age group

Adult

### Sex

All

### Key exclusion criteria

1. Body mass index (BMI) less than 18.0 or 31.0 (kg/m<sup>2</sup>)
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)

**ROR**

<https://ror.org/05m7pjf47>

**Funder(s)****Funder type**

Industry

**Funder Name**

Monaghan Mushrooms (Ireland)

**Results and Publications****Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration