

# The effects of a probiotic and vitamin D intervention in healthy adults on biochemical markers and metabolomic profiles

<b>Submission date</b> 14/07/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/07/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 21/07/2010	<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  
Dublin  
Ireland  
D4

## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

## Study information

**Scientific Title**

The effects of a probiotic and vitamin D intervention in healthy adults on biochemical markers and metabolomic profiles: a double-blind, randomised placebo-controlled trial carried out in two centres

**Study objectives**

The aim of this study is to investigate if a 4 week supplementation intervention with vitamin D or a probiotic alters biomarkers of the metabolic syndrome and the metabolomic profiles.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

UCD Research Ethics Committee approved on the 13th October 2006 (ref: HREC-39-06-Gibney)

**Study design**

Double-blind randomised placebo-controlled trial

**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**

Metabolic syndrome biomarkers

**Interventions**

The four treatment groups were defined as follows:

1. Treatment group 1: received daily vitamin D3 (15 µg) and probiotic (Lactobacillus salivarius 109 cfu/5 g sachets suspended in maltodextrin)
2. Treatment group 2: received daily vitamin D3 and placebo probiotic (maltodextrin)
3. Treatment group 3: received daily vitamin D3 placebo and probiotic
4. Treatment group 4: received daily vitamin D3 placebo and probiotic placebo

The vitamin D3 and matching placebo were food grade and consumed in capsule form and were identical in appearance and taste, while the probiotic and probiotic/placebo (in powder form) was mixed with milk for consumption.

Treatment duration: 4 weeks.

**Intervention Type**

Supplement

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Probiotic, vitamin D

**Primary outcome measure**

Measurement of the following markers at the end of the 4 week intervention:

1. Leptin
2. Resistin
3. Adiponectin
4. Interleukin-6 (IL-6)
5. C-reactive protein (CRP)
6. Tumour necrosis factor-alpha (TNFa)
7. Insulin
8. C-peptide
9. 25-hydroxy vitamin D (25(OH)D)
10. Triglyceride (TAG)
11. Non-esterfied fatty acids (NEFA)
12. Glucose

**Secondary outcome measures**

No secondary outcome measures

**Overall study start date**

01/11/2006

**Completion date**

01/09/2009

**Eligibility****Key inclusion criteria**

1. Healthy male and females aged 18 - 75 years
2. Free living
3. Fluent in English

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

160

**Key exclusion criteria**

1. Body mass index less than 18.5 or greater than 30.0 (kg/m<sup>2</sup>)
2. Iron deficiency anaemia (haemoglobin less than 12 g/dl for males, less than 11 g/dl for females)
3. Any chronic or infectious disease and any prescribed medication for such (contraceptive pills were permitted)
4. Pregnant or lactating females
5. Persons using hormone replacement therapy

**Date of first enrolment**

01/11/2006

**Date of final enrolment**

01/09/2009

**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**

Government

**Funder Name**

Department of Agriculture, Food and Fisheries (Ireland) - research grant under the Food Institutional Research Measure (ref: 06RDD417)

## **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