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

Submission date
14/07/2010

Recruitment status
No longer recruiting

Registration date
21/07/2010

Overall study status
Completed

Last Edited
21/07/2010

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
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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^2)
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