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A study of the biological availability of protein-derived ingredients

Submission date
05/12/2014

Recruitment status
No longer recruiting

Registration date
13/04/2015

Overall study status
Completed

Last Edited
14/04/2015

Condition category
Other

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

Plain English summary of protocol

Background and study aims
Milk is an excellent source of protein and other nutrients. Many proteins found in milk are caseins. These can be broken down into protein fragments, or peptides. Bioactive peptides are protein fragments that have a beneficial effect on health. There is evidence to suggest that casein bioactive peptides have beneficial effects on, for example, the cardiovascular system (for example, lowering blood pressure), immune system and nervous system. However, to fully understand these effects we need to find out how many of these bioactive peptides are available for use by the body once consumed. This study aims to achieve a greater understanding of the behaviour of a bioactive casein hydrolysate by examining the appearance of metabolic products in the circulation in a group of healthy individual's.

Who can participate?
Healthy Caucasian adults aged 18-65 years

What does the study involve?
Participants are randomly allocated to consume one of three test drinks (labelled caseins containing bioactive peptides, labelled caseins that have not been broken down, or unlabelled caseins) on three separate test days in random order. After fasting overnight, blood samples are taken from each participant over a period of 4 hours. Participants then come back for a second and third visit so that all drinks will have been consumed in random order by the end of the study.

What are the possible benefits and risks of participating?
There are no direct benefits to the participant, rather this study is to help researchers gain a better understanding of how ingredients that are potentially beneficial work.

Where is the study run from?
UCD Institute of Food and Health at University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
December 2014 to December 2018

Who is funding the study?
Food for Health (Ireland)

Who is the main contact?
Dr Lorraine Brennan
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Contact information

Type(s)
Scientific

Contact name
Dr Lorraine Brennan

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Contact details
UCD
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Ireland
D4

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Investigating the metabolic end products of casein-derived bioactive peptides

Acronym
FHIGM

Study objectives
To identify metabolic end products after consumption of milk casein-derived bioactive peptides

Ethics approval required
Old ethics approval format

Ethics approval(s)
Human Research Ethics Committee in University College Dublin (UCD), 17/10/14, ref: LS-14-34-Drummond-Brennan.

Study design
This is a randomised, crossover dietary intervention study

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Quality of life

Participant information sheet

Health condition(s) or problem(s) studied
Healthy subjects

Interventions
Participants will be randomised to receive the three test drinks (labelled caseins containing bioactive peptides, labelled caseins that have not been broken down, or unlabelled caseins) in random order, in a crossover fashion.

Intervention Type
Supplement

Primary outcome measure
Appearance of casein-derived metabolites and fragments thereof in the plasma postprandially.

Study subjects will attend the intervention suites in our research centre. At time 0, 10, 15, 30, 60, 90, 120, 180 and 240 minutes blood samples will be collected. Analysis will be performed at all timepoints.

Secondary outcome measures
Postprandial dietary nitrogen metabolism and hormonal profiles.

Overall study start date
05/12/2014

Completion date
31/12/2018

Eligibility

Key inclusion criteria
Healthy male and females free-living Caucasians aged 18-65 years

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
10

Key exclusion criteria
1. A body mass index (BMI) <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
01/01/2015

Date of final enrolment
01/01/2016

Locations

Countries of recruitment
Ireland

Study participating centre
UCD Institute of Food and Health
Dublin
Ireland

Sponsor information

Organisation
Food for Health Ireland

Sponsor details
UCD Institute of Food and Health
Level 2
Science Centre South
UCD
Dublin 4
Ireland
D4

Sponsor type
University/education

ROR
https://ror.org/01nvbq395

Funder(s)

Funder type
Research organisation

Funder Name
Food for Health (Ireland)

Results and Publications

Publication and dissemination plan
It is intended that the results of this study will be published in an academic journal.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available