

A study of the biological availability of protein-derived ingredients

Submission date 05/12/2014	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 13/04/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 14/04/2015	Condition category Other	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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
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Additional identifiers

Protocol serial number
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

Study type(s)

Quality of life

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(s)

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.

Key secondary outcome(s)

Postprandial dietary nitrogen metabolism and hormonal profiles.

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Upper age limit

65 years

Sex

All

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

ROR

<https://ror.org/01nvbq395>

Funder(s)

Funder type

Research organisation

Funder Name

Food for Health (Ireland)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available