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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

### ORCID ID
https://orcid.org/0000-0002-7711-7499

### Contact details
UCD
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# Additional identifiers

# 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.

### Primary study design
Interventional

### Study design

This is a randomised, crossover dietary intervention study

### 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