ISRCTN61079365 https://doi.org/10.1186/ISRCTN61079365

Milk proteins for glycemic management

Submission date	Recruitment status	[_] Prospectively registered
19/12/2016	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/12/2016	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/01/2019	Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims
Milk is an excellent source of protein and other key nutrients. Many proteins found in milk are caseins, which can be broken down into protein fragments (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 health, in particular the cardiovascular (circulatory) system and immune system. Some research has suggested that milk-derived protein supplements (hydrolysates) may have potential health benefits in terms of managing blood sugar levels. The aim of this study is to examine the ability of three different types of protein drinks to help maintain good blood sugar control.

Who can participate?
Healthy adults aged between 40 and 65 years.

What does the study involve?
Participants are randomly allocated receive three treatments in a random order. Each treatment lasts for three days and there is day period between each treatment where participants follow their normal diet. The first treatment involves drinking a protein drink containing intact casein twice a day at breakfast time and in the evening for three days. The second and third treatments involve drinking a protein drink containing protein hydrolysate A and protein hydrolysate B respectively (two different milk-derived protein supplements). The study period lasts for a total of 14 days, during which participants wear a special device which automatically and continuously monitors their blood sugar levels.

What are the possible benefits and risks of participating?
There are no direct benefits to the participants but this study should help researchers gain a better understanding of how ingredients that are potentially beneficial work. There are no notable risks involved with participating.

Where is the study run from?
University College Dublin (Ireland)

When is the study starting and how long is it expected to run for?
June 2016 to June 2018

Who is funding the study?
Enterprise Ireland (Ireland)

Who is the main contact?
Professor Lorraine Brennan

Contact information

Type(s)
Scientific

Contact name
Prof Lorraine Brennan

Contact details
University College Dublin Institute of Food and Health
Dublin
Ireland
D4

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CGM

Study information

Scientific Title
Examination of the effect of milk proteins on glycemic management

Study objectives
A protein hydrolysate will help glycemic management over and above the intact parent protein.

Ethics approval required
Old ethics approval format

Ethics approval(s)
UCD Human Ethics committee, 12/04/2016, ref: LS-16-13-Brennan

Study design
Randomised cross over intervention study

Primary study design

Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Home

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Diabetes risk

Interventions
Participants will be randomised to receive three treatments in a random order. There will be a washout period of 2 days between each arm, where participants follow their normal diet.

Treatment 1: Protein drink containing intact casein
Treatment 2: Protein drink containing protein hydrolysate A
Treatment 3: Protein drink containing protein hydrolysate B

In all treatments, the protein drink will be consumed twice daily for 3 days as part of study breakfast and evening meals.

Follow up involves wearing the FreeStyle Libre continuous glucose monitoring system for 14 days in order to monitor glucose levels.

Intervention Type
Supplement

Primary outcome measure
Glucose levels are measured using the FreeStyle Libre continuous glucose monitoring system continuously for the 14 days of the study.

Secondary outcome measures
Glucose control throughout the day is measured using the FreeStyle Libre continuous monitoring system continuously for the 14 days of the study.

Overall study start date
01/06/2016

Completion date
01/06/2018

Eligibility

Key inclusion criteria
Healthy adults aged 40-65 years

Participant type(s)
Healthy volunteer

Age group
Adult

Sex
Both

Target number of participants
20

Key exclusion criteria
1. BMI < 25kg/m2, BMI >35kg/m2,
2. Any diagnosis of disease or the taking of any medication (except the OCP)
3. Pregnancy or lactation
4. An allergy or intolerance to dairy or wheat products
5. Known allergy to medical grade adhesive

Date of first enrolment
01/10/2016

Date of final enrolment
01/09/2017

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Belfield
Dublin
Ireland
D4

Sponsor information

Organisation
Food for Health Ireland

Sponsor details
University College Dublin Institute of Food and Health
Dublin
Ireland
D4

Sponsor type
University/education

ROR
https://ror.org/01nvbq395

Funder(s)

Funder type
Government

Funder Name
Enterprise Ireland

Alternative Name(s)

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Ireland

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/06/2019

Individual participant data (IPD) sharing plan
The current data sharing plans for the current study are unknown and will be made available at a later date.

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2019		Yes	No