

# Milk proteins for glycemic management

<b>Submission date</b> 19/12/2016	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 21/12/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 07/01/2019	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

## 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

**Protocol serial number**  
CGM

## Study information

**Scientific Title**  
Examination of the effect of milk proteins on glycemc management

**Study objectives**  
A protein hydrolysate will help glycemc 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

**Study type(s)**  
Other

**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(s)**

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

### **Key secondary outcome(s)**

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

### **Completion date**

01/06/2018

## **Eligibility**

### **Key inclusion criteria**

Healthy adults aged 40-65 years

### **Participant type(s)**

Healthy volunteer

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **Key exclusion criteria**

1. BMI < 25kg/m<sup>2</sup>, BMI >35kg/m<sup>2</sup>,
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

**ROR**

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

## Funder(s)

**Funder type**

Government

**Funder Name**

Enterprise Ireland

**Alternative Name(s)**

The Enterprise Ireland

**Funding Body Type**

Government organisation

### Funding Body Subtype

National government

### Location

Ireland

## Results and Publications

### 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?
<a href="#">Results article</a>	results	01/01/2019		Yes	No