ISRCTN15620029 https://doi.org/10.1186/ISRCTN15620029

Investigation of glucose and insulin levels, using oral glucose tolerance testing, in response to active compounds derived from protein

Submission date
23/03/2021

Recruitment status
No longer recruiting

Registration date
31/03/2021

Overall study status
Completed

Last Edited
06/04/2021

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
Obesity and type 2 diabetes are considered global public health issues and the concern needs to be urgently addressed. The number of people with type 2 diabetes is increasing and new preventative solutions are necessary. Plant and dairy proteins and their hydrolysates may have possible health benefits. This study aims to examine the effects of three different protein drinks (with different compositions) on the body's ability to control circulating glucose levels (and other related molecules). Protein hydrolysates are proteins that have been broken down by enzymes into smaller molecules such as amino acids or peptides, like digestion. Enzymes are molecules that help to speed up chemical reactions and break down large molecules like proteins into smaller molecules like hydrolysates. The aim of this study is to explore if a rice protein hydrolysate, on its own or in combination with a milk protein, has the potential to manage blood sugar levels.

Who can participate?
Adults aged between 18 and 45 who have a body mass index (BMI) between 18 and 30 kg/m²

What does the study involve?
Initially, potential volunteers will be invited for a screening test where the researchers will measure their weight, height, waist, and hips and explain the study in detail to them. After successful screening, if they are still interested in taking part, they will come into the Intervention suite in the Science building in University College Dublin, in the morning, having fasted overnight (for 9 hours). The researchers will give the participant one of the three test drinks (rice protein, milk protein or a combination of both) and a glucose drink. A cannula (a small thin tube) will be inserted into their arm and will remain there over the next 2 hours. The researchers will take several blood samples from this throughout the day without having to pierce the skin multiple times. 30 ml of blood will be taken at six times throughout the 2 hours; a total of 180 ml of blood. A bed will be provided to rest on. A desk will also be available if volunteers wish to read, study or use a laptop. There will be wireless internet available and if participants wish to bring a book or DVDs to watch, they are very welcome to do so. There are three different test drinks, and each volunteer will come in for 2 hours on each of the three test

days so that they will have consumed all the drinks in a random order by the end of the study. If they change their mind at any point, they may withdraw at any stage throughout the study and are under no obligation to complete it.

What are the possible benefits and risks of participating?
There are no notable benefits for those involved in the study. They will get the opportunity to learn about research in this area. Furthermore, their participation in this project may help to contribute to a better understanding of the effects of proteins for managing blood glucose. This information may ultimately be important in the long-term to help to develop more effective strategies to prevent type 2 diabetes, for example, the development of new foods.
Whilst there are no risks, some people may find it uncomfortable to give blood samples. They can be assured that the researchers are experienced and will ensure they are comfortable with all procedures and assessments. If they are troubled by any of the procedures, the researchers would advise leaving the study. Women who are pregnant, breastfeeding, or planning a pregnancy are excluded from the study and if a subject becomes pregnant over the course of the study they must inform the director and leave the study immediately. It is important for volunteers to understand that this is not intended to replace any routine blood tests they or their doctor would have arranged. They will not receive individual results, so this cannot be treated as part of a routine healthcare screening. Milk proteins derived from normal cow's milk and rice protein hydrolysates have been used in previous studies with no negative outcomes. If at any stage they have an adverse reaction, they should stop taking the drink and immediately inform the researcher who will instruct them on what to do.

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

When is the study starting and how long is t expected to run for?
July 2017 to September 2018

Who is funding the study?
The Irish Research Council's Enterprise Partnership Scheme with Kerry Group (Ireland)

Who is the main contact?
Dr Claire Erraught
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Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
A randomized, controlled, crossover design study to investigate postprandial glucose levels of participants in response to proteins, using an oral glucose tolerance test (OGTT)

Acronym
UCD Protein Study

Study objectives

To test a novel rice derived hydrolysed protein on its own or in combination with an intact milk-derived protein's ability to control blood glucose levels versus an intact milk-derived protein alone.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 02/10/2017, University College Dublin Human Research Ethics Committee (Human Research Ethics Committee – Sciences
UCD Office of Research Ethics, Roebuck Castle, University College Dublin, Belfield, Dublin 4, Ireland; +353 (0)1 716 8767; hrec@ucd.ie), ref: LS-17-75-Erraught-Brennan

Study design
Single-centre randomized crossover single-blinded interventional trial

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Postprandially stimulated insulin secretion and blood glucose control

Interventions
An Oral Glucose Tolerence Test (OGTT) accompanied by a protein drink.
Drink 1 – 75 g glucose in 200 ml water + 15 g Intact Whey protein in 100 ml water
Drink 2 – 75 g glucose in 200 ml water + 15 g Hyprol 5312 in 100 ml water
Drink 3 – 75 g glucose in 200 ml water + 7.5 g Hyprol 5312 + 7.5 g Intact Whey protein in 100 ml water
Whey is the dairy based protein and the Hyprol 5312 is a hydrolysed rice derived protein.

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pierce the skin multiple times. 30 ml of blood will be taken at six timepoints throughout the two hours; a total of 180 ml of blood. A bed will be provided to rest on. A desk will also be available if volunteers wish to read, study or use a laptop. There will be wireless internet available and if participants wish to bring a book or DVDs to watch, they are very welcome to do so. There are three different test drinks, and each volunteer will come in for 2 hours on each of the three test days, so that they will have consumed all drinks, in a random order, by the end of the study. If they change their mind at any point, they may withdraw at any stage throughout the study and are under no obligation to complete it.

Intervention Type
Other

Primary outcome measure
Blood glucose levels measured using venous blood samples taken at baseline, then 15, 30, 60, 90- and 120-min post intervention

Secondary outcome measures
1. Plasma insulin response measured using venous blood samples taken at baseline, then 15, 30, 60, 90- and 120-min post intervention
2. Amino-acid, fatty acid or TCA cycle intermediate metabolism measured using venous blood samples taken at baseline, then 15, 30, 60, 90- and 120-min post intervention
3. C-peptide production measured using venous blood samples taken at baseline, then 15, 30, 60, 90- and 120-min post intervention

Overall study start date
01/07/2017

Completion date
01/09/2018

Eligibility

Key inclusion criteria
1. Aged >18 and <45 years
2. BMI >18.5 and < 30 kg/m²
3. Generally healthy free living in the community
4. Males and females

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
24

Total final enrolment
24

Key exclusion criteria
1. Aged below 18 years and above 45 years
2. BMI > 30 kg/m², <18.5kg/m²
3. Diagnosis chronic or infectious disease
4. Taking of any medication (exception OCP)
5. Pregnancy or breastfeeding
6. Have an allergy or intolerance to dairy or rice products

Date of first enrolment
01/10/2017

Date of final enrolment
31/03/2018

Locations

Countries of recruitment
Ireland

Study participating centre
University College Dublin
Belfield,
Dublin 4
Ireland
Dublin
Ireland
Dublin 4

Sponsor information

Organisation
University College Dublin

Sponsor details
Institute of Food & Health
Science Centre South
Belfield
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Ireland

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Sponsor type
University/education

Website
https://www.ucd.ie/foodandhealth/

ROR
https://ror.org/05m7pjf47

Funder(s)

Funder type
Research council

Funder Name
Irish Research Council for Science, Engineering and Technology

Alternative Name(s)
IRCSET

Funding Body Type
Private sector organisation

Funding Body Subtype
Other non-profit organizations

Location
Ireland

Funder Name
Kerry Group PLC

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal. Additional documents are not available.

Intention to publish date

01/07/2021

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available as consent from participants does not include this.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet			06/04/2021	No	Yes