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The effect of hydrolysed pea protein on postprandial blood glucose profile in healthy adults

Submission date
05/05/2025

Recruitment status
No longer recruiting

Registration date
22/05/2025

Overall study status
Completed

Last Edited
06/05/2025

Condition category
Nutritional, Metabolic, Endocrine

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

Plain English summary of protocol

Background and study aims
After eating a meal, especially one high in carbohydrates like bread or pasta, our blood sugar levels naturally rise. For some people, especially those at risk of type 2 diabetes, these rises can be too high or last too long, which can be harmful over time. What we eat alongside carbohydrates can affect how our body handles sugar. Proteins, including those from plants, may help reduce the rise in blood sugar after eating. Pea protein is a plant-based protein that is popular for being sustainable, allergy-friendly, and suitable for vegetarians and vegans. This study is particularly interested in hydrolysed pea protein, which is a type of protein that has been broken down into smaller units called peptides. These smaller fragments may have enhanced effects on digestion and blood sugar compared to regular pea protein isolate. The study aims to find out whether hydrolysed pea protein helps reduce blood sugar levels after a meal, and how it compares to regular pea protein, whey protein (from animal source), and a control drink (water). It will also look at other substances in the blood that are linked to how the body controls sugar and appetite

Who can participate?
Healthy adult volunteers

What does the study involve?
The study compares four conditions: a carbohydrate meal with either 30 g pre-hydrolysed pea protein drink, 30 g non-hydrolysed pea protein isolate drink, 30 g whey protein drink, or water (Control). Each participant attended four randomly allocated blinded sessions over two weeks, with standardized carbohydrate content and a minimum of 2 days between sessions for washout.

What are the possible benefits and risks of participating?
No benefits and risks given at publication

Where is the study run from?
University of Leeds, School of Food Science and Nutrition, UK

When is the study starting and how long is it expected to run for?
November 2024 to September 2025

Who is funding the study?
Libyan Embassy, UK (PhD Scholarship to Arig Elbira)

Who is the main contact?
Arig Elbira, fs19aaae@leeds.ac.uk

Contact information

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Public, Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
2148

Study information

Scientific Title
Postprandial glycaemic response to hydrolysed pea protein in healthy adults: a randomised, double-blind, controlled, crossover trial

Acronym
HYPP-GLY Study

Study objectives
Hydrolysed pea protein will reduce postprandial blood glucose levels more effectively than non-hydrolysed pea protein when co-ingested with a carbohydrate-rich meal in healthy adults.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 01/04/2025, Business, Environment, Social Sciences (BESS+ FREC) Faculty Research Ethics Committee (FREC) (University of Leeds, Woodhouse Ln, Woodhouse, Leeds, LS29JT, United Kingdom; +44(0)113 343 0524; ResearchEthics@leeds.ac.uk), ref: 2148

Study design
Single-centre double-blinded randomized controlled crossover trial

Primary study design
Interventional

Study type(s)
Prevention, Efficacy

Health condition(s) or problem(s) studied
Reduction of postprandial glycaemia in healthy adult

Interventions
The study compared four conditions: a carbohydrate meal consumed together with (1) 30 g pre-hydrolysed pea protein drink , (2) 30 g non-hydrolysed pea protein isolate drink, (3) 30 g whey protein drink, and (4) water (Control). The total carbohydrate content was standardized to 75 g across all test conditions (white bread and maltodextrin). All four drinks were flavour-masked to ensure a double-blind design. The order of interventions was randomized using pre-generated sequences from an online program. Each participant attended four separate sessions over approximately two weeks, with a minimum of 2 days between sessions to allow for washout.

Intervention Type
Supplement

Primary outcome(s)
Postprandial glucose levels will be measured using two methods:
1. Continuous Glucose Monitor devices (CGMs) for a total of 14 days
2. Glucometer using strips at baseline and every 15 min for a total of 3h post-meal

Key secondary outcome(s))
1. Insulin and satiety hormones will be measured from capillary blood samples collected via the finger-prick method at baseline and every 15 min for a total of 3h post-meal
2. Blood pressure will be measured using an automatic device at baseline and every 30 min for a total of 3h post-meal
3. Satiety score will be measured using a Visual Analogue Scale (VAS) at baseline and every 30 min for a total of 3h post-meal

Completion date
01/09/2025

Eligibility

Key inclusion criteria
1. Adults aged between 18 – 56 years old
2. Normal rage of body weight with BMI <30 kg/m2.
3. Be in general good health (with no known food allergies/intolerances)
4. Normal range of fasting blood glucose levels (<5.6 mmol/L)
5. Not taking any medication/s known to affect blood pressure, blood glucose (like diabetic medication) or cholesterol.

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
56 years

Sex
All

Key exclusion criteria
1. BMI >30 kg/m²
2. Elevated fasting blood glucose (above 5.5 mmol/L)
3. Pregnancy
4. Smoking
5. Chronic diseases
6. Allergies and medication use known to affect food digestion, appetite, food sensory perception, or glucose metabolism
7. Individuals who engage in regular high-intensity athletic training or competitive sports
8. Recent blood donation (<3 months)
9. Participation in simultaneous studies

Date of first enrolment
07/04/2025

Date of final enrolment
30/05/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
School of Food Science and Nutrition
University of Leeds, Woodhouse Ln, Woodhouse
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Sponsor information

Organisation
University of Leeds

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
Libyan Embassy

Results and Publications

Individual participant data (IPD) sharing plan
The data generated and analysed during this study will be published as averages rather than individual data or participant identity to ensure anonymity.

IPD sharing plan summary
Published as a supplement to the results publication

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes