

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

Submission date 05/05/2025	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 22/05/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 06/05/2025	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Individual participant data
		<input checked="" type="checkbox"/> 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

Type(s)

Public, Principal Investigator

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number**ClinicalTrials.gov number**

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised cross over trial

Study setting(s)

University/medical school/dental school

Study type(s)

Prevention, Efficacy

Participant information sheet

See study outputs table

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 measure

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

Secondary outcome measures

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

Overall study start date

01/11/2024

Completion date

01/09/2025

Eligibility

Key inclusion criteria

1. Adults aged between 18 – 56 years old
2. Normal range 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

Age group

Adult

Lower age limit

18 Years

Upper age limit

56 Years

Sex

Both

Target number of participants

16

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**

England

United Kingdom

Study participating centre
School of Food Science and Nutrition
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Sponsor information

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Sponsor type
University/education

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ROR
<https://ror.org/024mrx33>

Funder(s)

Funder type
Government

Funder Name
Libyan Embassy

Results and Publications

Publication and dissemination plan

Planned publication in a peer-reviewed journal by July 2025

Intention to publish date

15/07/2025

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