ISRCTN15239656 https://doi.org/10.1186/ISRCTN15239656

Assessing the metabolic effect of sustainable proteins

Submission date 07/10/2025	**Recruitment status** No longer recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/10/2025	**Overall study status** Ongoing	
Last Edited 20/04/2026	**Condition category** Nutritional, Metabolic, Endocrine	

Plain English summary of protocol

Background and study aims

Red meat consumption has increased around the world. Current meat production practices are environmentally unsustainable. A growing awareness of potential health risks linked to high red and processed meat consumption has prompted many individuals to seek alternative sources of protein. As a result, there has been a shift towards more sustainable and health-conscious protein options, such as fermented products and plant-based proteins. Moreover, sustainable, plant-based proteins may provide other health benefits such as reducing cholesterol and improving blood sugar control, potentially affecting long-term health outcomes. It is unclear how the human body digests these new protein sources and how this impacts subsequent metabolic responses. The aim of the current study is to understand how meat alternatives, both fermented and non-fermented, are digested and metabolised, compared with red meat, in humans.

Who can participate?

You may be eligible to participate if you meet the following criteria:

1. Individuals aged between 18-65 years (inclusive)
2. Body mass index (BMI) of 18.5-29.9 kg/m2

What does the study involve?

Screening Visit (Up to 1 hour):

If you are eligible and decide to participate in this study, you will be invited to attend the NIHR Imperial Clinical Research Facility at Hammersmith Hospital (W12 0HS) for a screening visit. You will be able to ask us any further questions you might have about the study. You will also receive a hard copy of this information sheet. After all your questions have been answered and if you are still willing to participate in the study, you will be asked to sign a consent form.

You will then go through a health screening for the study where you will be interviewed and examined by one member of the research team. You will have a blood test (to ensure that you are not anaemic or diabetic) and height, weight, and blood pressure measurements will be taken. All women of childbearing age will have a pregnancy test. During this visit, you will complete a brief study eligibility questionnaire in which you will need to complete information about any medication you are taking, past medical and family history of any conditions and GP details. The results of these measurements (weight, height, blood pressure and pregnancy test)

will be recorded in this questionnaire.
You will be informed (by phone or email) by a member of the research team whether the blood test, blood pressure and body weight measurements results make you eligible to participate in the study. Your GP will receive a copy of your blood test results.

Online dietary recall tool
Libro is an easy-to-use, self-reporting online tool that records what a person eats and drinks. It can be used on a smartphone via an application and you will be provided with login details. You will not be required to input your email address or name. You will record what you have been eating and drinking during the 4 days before each study visit.

Dietary Interventions
If you are eligible and would like to participate in the study, you will be invited to the NIHR Imperial Clinical Research Facility for three separate visits. During these visits, you will be given three different diets. These will either contain A: Fungi-based fermented sustainable protein source product called Matr, B: Matr's unfermented alternative or C: Beef. Matr is certified and sold for human consumption, predominantly in Denmark. Outside of your study visits, you may continue to follow your usual diet throughout the duration of the study.

Study Visits 1-3
Each visit will follow the same protocol, listed below.
Four days before you arrive for your visit, we will ask you to start recording your dietary intake using the Libro application. The day before you are due to come for your visit, we will also ask you to collect a stool sample at home using the kit provided by the team and bring this to your visit the next day. We will also ask you to avoid alcohol and strenuous exercise the day before your visit.
Day 1: You will come to the unit around 3 pm. Women of childbearing age will be asked to provide a urine sample. You will be served an evening meal around 5 pm and asked to consume this in 15 minutes. You will be served another snack at 8 pm and asked to consume this in 15 minutes.
Each visit will last around 25 hours. You cannot leave the facility during this time. You will stay overnight in a private ensuite room with shower facilities (towels provided). Please bring anything you require to be comfortable and have a good night's sleep. This may include:
1. Pyjamas
2. An eye mask and ear plugs
3. Toiletries (including shower gel/shampoo, should you wish to shower)
3. A change of clothes
4. Entertainment (e.g. laptop, chargers for devices, book, headphones)
Day 2: At approximately 8:30 am, your weight and blood pressure will be measured and you will be asked to collect your urine throughout the day in a large container. Following this, a member of the research team will place a cannula (a small, flexible plastic tube) for testing in your arm that will stay in place during the study visit, which will allow us to take blood without causing you further discomfort.
Two fasted blood samples (10 ml each) will be collected through this cannula and you will be given a questionnaire on your appetite and a breath test to complete. You will be given breakfast around 9am. After breakfast, at regular intervals, you will have a blood sample taken (10 ml of blood, duration: 5 minutes) and complete an appetite questionnaire (duration: 2 minutes) and a breath test (duration: 1 minute). Five measurements will be taken between breakfast and lunch. Lunch will be served around midday, and five further measurement will be taken after lunch.
In total, 120 ml (8 tablespoons) of blood will be taken, and 12 questionnaires and breath tests will be completed during each study visit (for further clarification please refer to the sample

collection outline below).
A final meal will be served around 3 pm. This is called an ad-libitum food test and will help us to measure your food intake. You will be asked to consume the bowl of pasta until you are comfortably full. After this meal, the cannula will be removed, and you will be free to leave.

What are the possible benefits and risks of participating?
The study will not directly benefit you. However, we hope that the information we will gather through your participation will help us identify how sustainable proteins are digested in the human body which could assist with the formulation of sustainable proteins in the future.
Blood sampling may produce mild discomfort when the needle is inserted, possible bruising and localised infection. To reduce any of these risks, blood sampling will only be performed by appropriately trained doctors, nurses, or members of research team under aseptic conditions. All meals provided by the study team are safe for human consumption and do not pose any risk to human health.

Where is the study run from?
Imperial College London (UK)

When is the study starting and how long is it expected to run for?
This study will begin recruitment in November 2025 and will run until June 2026.

Who is funding the study?
The Bezos Centre for Sustainable Proteins (UK)

Who is the main contact?
1. Dr Jennifer Pugh, jennifer.pugh3@nhs.net
2. Dr Aygul Dagbasi, aygul.dagbasi@nhs.net

Contact information

Type(s)
Public, Scientific

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Additional identifiers

Integrated Research Application System (IRAS)
318744

Protocol serial number
EDGE ID: 179948

Study information

Scientific Title
Assessing the metabolic effect of sustainable proteins, compared with red meat, in healthy participants

Acronym
AMES-PRO

Study objectives
The primary objectives are to measure the glyceamic and triglyceride responses to novel proteins, in both fermented- and non-fermented-forms, compared with red meat.

The secondary objectives are:
1. To assess amino acid bioavailability and absorption by measuring changes in postprandial amino acids
2. To monitor changes in gut microbial fermentation using breath hydrogen
3. To assess how the gut microbiome influences metabolic response by analysing stool microbiota
4. To measure appetite using visual analogue scales (VAS) and energy intake via an ad libitum meal
5. To assess differences in metabolites produced via urine and serum metabolomic analysis

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 03/10/2025, East of Scotland Research Ethics Service (Tayside medical Science Centre, Dundee, DD1 9SY, United Kingdom; -; tay.eosres@nhs.scot), ref: 25/ES/0080

Primary study design
Interventional

Study design
Randomized controlled cross-over study

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Prevention of metabolic disease in currently healthy volunteers

Interventions
This pilot study will be a randomised-controlled cross-over study recruiting 10 healthy participants consisting of three visits that will take place over a period of a maximum of 2 months.

The order of intervention will be randomly allocated using Sealed Envelope software to avoid order effects. The three interventions will be meals composed of MATR x 2 (fermented and unfermented product) or red meat (A: fermented meat alternative, B: unfermented meat alternative or C: meat).

Intervention Type
Other

Primary outcome(s)
Glucose and triglyceride incremental area under the curve (iAUC) measured using blood samples at 12 timepoints (-15, -10, 15, 30, 60, 120, 180, 195, 210, 240, 300, 360) throughout the three study visits

Key secondary outcome(s)
1. Weight measured by bioelectrical impedance scale at each of the three study visits
2. Body composition (fat mass, lean mass) measured by bioelectrical impedance scale at each of the three study visits
3. Blood pressure measured using a blood pressure cuff at each of the three study visits
4. Insulin, free fatty acids and circulating amino acids measured in the blood at 12 timepoints (-15, -10, 15, 30, 60, 120, 180, 195, 210, 240, 300, 360) throughout the three study visits
5. Breath hydrogen measured using a Gastrolyzer machine at 12 timepoints (-15, -10, 15, 30, 60, 120, 180, 195, 210, 240, 300, 360) throughout the three study visits
6. Appetite measured using visual analogue scales at 12 timepoints (-15, -10, 15, 30, 60, 120, 180, 195, 210, 240, 300, 360) throughout the three study visits
7. Energy intake measured using an ad-libitum meal at the end of each of the three study visits
8. Stool microbiota composition measured in the stool samples provided at the beginning of each of the three study visits
9. Metabolite concentrations measured in the urine and serum samples collected at each of the three study visits

Completion date
01/12/2026

Eligibility

Key inclusion criteria
1. Body mass index (BMI) of 18.5-29.9 kg/m2
2. Individuals aged between 18-65 years (inclusive)

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Weight change of >3 kg in last 3 months
2. HbA1c exceeding 41 mmol/mol (8.5%)
3. Bowel reconstruction surgery
4. Vegan or vegetarians
5. Food allergies or intolerances
6. Blood donation in the last 3 months
7. Current smokers
8. Substance abuse
9. Excess alcohol intake (>14 units per week)
10. Pregnancy or breastfeeding
11. Cardiovascular disease
12. Cancer
13. Kidney failure
14. Participation in another research study in the past 12 weeks
15. Diagnosed gastrointestinal conditions
16. Use of antibiotics in the past 3 months
17. Use of anti-inflammatory drugs or steroids or thyroid hormones
18. New medication in the past 3 months

Date of first enrolment
01/12/2025

Date of final enrolment
01/06/2026

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
NIHR Imperial Clinical Research Facility
Hammersmith Hospital
Du Cane Rd
Shepherd's Bush
London
England
W12 0HS

Sponsor information

Organisation
Imperial College London

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Research organisation

Funder Name
Bezos Centre for Sustainable Protein

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from the study researchers (Dr Jennifer Pugh, jennifer.pugh3@nhs.net or Dr Aygul Dagbasi,aygul.dagbasi@nhs.net).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	version 3	25/09/2025	08/10/2025	No	Yes
Participant information sheet	version 4		20/04/2026	No	Yes
Protocol file	version 4		20/04/2026	No	No