

Propionate and bone health

Submission date 05/03/2025	Recruitment status Recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 09/04/2025	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 09/04/2025	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Osteoporotic fractures are a major health issue in the UK, with over 500,000 cases each year. Postmenopausal women are at a higher risk due to the impact of menopause on bone health. This study aims to test a new dietary supplement called inulin-propionate ester (IPE) to see if it can improve bone health and prevent fractures in postmenopausal women.

Who can participate?

Postmenopausal women aged 50-75 years.

What does the study involve?

Participants will attend four visits at the NIHR Imperial Clinical Research Facility at Hammersmith Hospital. These visits include health screenings, blood and urine tests, and dietary assessments. Participants will take either the IPE supplement or a control substance daily for 8 weeks. Blood and stool samples will be collected regularly to measure health markers.

What are the possible benefits and risks of participating?

Participants may benefit from learning more about their health. However, there are some risks, such as mild discomfort from blood tests and potential side effects from the supplement, like bloating and flatulence. Any health issues discovered during the study will be communicated to the participant and their GP.

Where is the study run from?

The study is run from the NIHR Imperial Clinical Research Facility at Hammersmith Hospital (UK)

When is the study starting and how long is it expected to run for?

November 2021 to December 2026

Who is funding the study?

The study is funded by the Rosetrees Trust and the Stoneygate Trust (UK)

Who is the main contact?

Dr Edward Chambers, e.chambers@imperial.ac.uk

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

307502

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

21HH7302

Study information

Scientific Title

Increasing gut-derived propionate to improve bone health in postmenopausal women

Acronym

BOPRO

Study objectives

Dietary propionate supplementation with inulin-propionate ester (IPE) will improve bone turnover makers in postmenopausal women

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 06/06/2022, London - South East (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 2071048222; londonsoutheast.rec@hra.nhs.uk), ref: 21/LO/0913

Study design

Randomized parallel group trial

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of osteoporotic fractures in postmenopausal women

Interventions

Inulin-propionate ester (Intervention): 10 g/day for 8 weeks. Incorporated into habitual diet.
Cellulose (Control): 10 g/day for 8 weeks. Incorporated into habitual diet

Randomisation will be conducted using <https://www.sealedenvelope.com/>

Intervention Type

Supplement

Primary outcome(s)

1. Carboxy-terminal telopeptide of type I collagen (CTX-I) is measured at baseline, week 2, and week 8 in fasting and postprandial blood samples
2. N-telopeptide of type I collagen (NTX-I) is measured at baseline, week 2, and week 8 in fasting and postprandial blood samples
3. N-terminal propeptide of type I procollagen (PINP) is measured at baseline, week 2, and week 8 in fasting and postprandial blood samples
4. Osteocalcin is measured at baseline, week 2, and week 8 in fasting and postprandial blood samples
5. Bone specific alkaline phosphatase (BAP) is measured at baseline, week 2, and week 8 in fasting and postprandial blood samples
6. N-telopeptide of type I collagen (NTX-I) is measured at baseline, week 2, and week 8 in urine samples

Key secondary outcome(s)

1. Short chain fatty acids (SCFA) are measured in blood samples and stool samples at baseline and week 8
2. Glucose homeostasis is measured using blood glucose, insulin, HbA1c, and insulin-like growth factor 1 (IGF-1) at baseline and week 8
3. Immune function is measured using inflammatory cytokines and immune phenotyping of peripheral blood mononuclear cells (PBMCs) at baseline and week 8
4. Gut barrier function is measured using lipopolysaccharide (LPS) in blood samples and calprotectin and zonulin in stool samples at baseline and week 8
5. Calcium and Vitamin D metabolism is measured using parathyroid hormone and Vitamin D 25-hydroxy in blood samples at baseline and week 8

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Post-menopausal females (>5 years post-menopause)
2. Healthy non-obese volunteers (body mass index (BMI) of 20-30 kg/m²)
3. Age between 50-75 years (inclusive)
4. Non-diabetic (HbA1c <48 mmol/mol)

Participant type(s)

Healthy volunteer

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

50 years

Upper age limit

75 years

Sex

Female

Key exclusion criteria

1. Weight change of ≥ 3 kg in the preceding 2 months
2. Current smokers
3. Substance abuse
4. Excess alcohol intake
5. Cardiovascular disease
6. Cancer
7. Gastrointestinal disease e.g. inflammatory bowel disease or irritable bowel syndrome
8. Kidney disease
9. Pancreatitis
10. Use of medications likely to interfere with energy metabolism, appetite regulation and hormonal balance, including: anti-inflammatory drugs or steroids, antibiotics, androgens, phenytoin, erythromycin or thyroid hormones

Date of first enrolment

01/06/2025

Date of final enrolment

31/05/2026

Locations

Countries of recruitment

United Kingdom

England

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

Sponsor information

Organisation
Imperial College London

ROR
<https://ror.org/041kmwe10>

Funder(s)

Funder type
Charity

Funder Name
Rosetrees Trust

Alternative Name(s)
Rosetrees, Teresa Rosenbaum Golden Charitable Trust

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name

Stoneygate Trust

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed the current study will be available upon request from Dr Edward Chambers
e.chambers@imperial.ac.uk

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	30/05/2022	06/03/2025	No	Yes
Protocol file	version 1	09/11/2021	06/03/2025	No	No