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Propionate and bone health

Submission date 05/03/2025	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 09/04/2025	**Overall study status** Ongoing	
Last Edited 09/04/2025	**Condition category** Musculoskeletal Diseases	

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

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
307502

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
See outputs table

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 measure
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

Secondary outcome measures
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

Overall study start date
09/11/2021

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

Age group
Adult

Lower age limit
50 Years

Upper age limit
75 Years

Sex
Female

Target number of participants
28

Key exclusion criteria
1. Weight change of ≥ 3kg 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
England

United Kingdom

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

Sponsor details
Research Governance and Integrity Team
Imperial College London and Imperial College Healthcare NHS Trust
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Sponsor type
University/education

Website
https://www.imperial.ac.uk

ROR
https://ror.org/041kmwe10

Funder(s)

Funder type
Charity

Funder Name
Rosetrees Trust

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

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

Publication and dissemination plan
The findings of the research will be published in an open-access, peer-reviewed journal. In addition, we will be collaborating with patient groups and professional groups to disseminate the findings via multiple media channels such as patient association publications, print and broadcast media. All data will be anonymised prior to publication.

Intention to publish date
01/06/2027

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