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Gut microbial activity, lifestyle factors, and bone metabolism in premenopausal and postmenopausal women

Submission date
24/02/2026

Recruitment status
Recruiting

Registration date
29/05/2026

Overall study status
Ongoing

Last Edited
29/05/2026

Condition category
Musculoskeletal Diseases

[ ] 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
Short-chain fatty acids (SCFAs) are generally considered beneficial because they help lower inflammation, support gut barrier integrity, and may contribute to bone health by influencing bone turnover (the rate of bone formation and breakdown). Lower or disrupted SCFA production has been linked to higher inflammation and poorer metabolic health. Measuring SCFAs in this study will help us understand whether differences in SCFA levels play a role in bone health changes before and after menopause.
As women transition from pre- to post-menopause, significant changes occur in hormone levels, metabolism, and gut health. These changes may impact the production of SCFAs, compounds produced by gut bacteria that play an important role in bone turnover markers, inflammation control, and overall health.
This study aims to assess how menopausal ageing and lifestyle factors such as dietary fibre intake and physical activity influence SCFAs, bone turnover markers, and gut health markers. It will compare SCFA levels and bone turnover markers between premenopausal women (aged 18–40 years) and postmenopausal women (≥5 years post-menopause) aged 60 years and older. This research will provide insights into lifestyle strategies to support metabolic and skeletal health in ageing women.

Who can participate?
1. Premenopausal women aged 18–40 years
2. Postmenopausal women (≥5 years post-menopause) aged ≥60 years
3. BMI between 18.5 and 30 kg/m²
3. HbA1c <48 mmol/mol

What does the study involve?
If you do decide to participate, the study will consist of two separate study visits. We request that you do not start any new diets or intensive exercise regimes (dramatically increase the amount of exercise you do, for example, join a gym) in between the study visits, as this may give us conflicting results.

Visit 1 – Health Screening:
You will be asked to attend the NIHR Imperial Clinical Research Facility at Hammersmith Hospital, where you will be interviewed about your general health. You will have a blood test to confirm that you are non-diabetic, and your body weight and height will be recorded. Women of childbearing potential will complete a urinary pregnancy test. The duration of the study visit would be around 1 hour.

After confirming eligibility, you will receive:
1. A 7-day wearable physical activity monitor. The device is waterproof, and you will be asked to wear this on your wrist continuously for 7 days.
2. Access to an online food diary (https://intake24.org/) to track dietary intake for 7 days
3. A stool and urine sample kit for home collection. Detailed instructions on collection and storage will be provided.

Visit 2 – Study Assessment:
This visit will take place after your 7-day monitoring period. You will return your stool and urine samples, and we will collect a blood sample. This blood sample will be used to analyse several markers related to bone and gut health, such as:
1. CTX (C-terminal telopeptide): a marker of bone resorption, which is the process of old bone being broken down.
2. PINP (procollagen type 1 N-terminal propeptide): a marker of new bone formation.
3. Osteocalcin: a marker of new bone formation.
4. PTH (parathyroid hormone): a hormone that helps regulate calcium levels.
5. Vitamin D: important for bone strength and calcium absorption.
6. LPS (lipopolysaccharide): a component of bacteria in the gut. Higher levels in blood are used as a marker of intestinal permeability, i.e., a leaky gut.
Your urine sample will be used to measure NTX (N-terminal telopeptide): a marker of bone resorption.
Your stool sample will be used to measure levels of SCFA and intestinal permeability markers (calprotectin and zonulin).
Stool calprotectin and zonulin are biomarkers related to gut health, where LPS can indicate a leaky gut, calprotectin is a marker of intestinal inflammation, and zonulin is a marker of intestinal permeability.

What are the possible benefits and risks of participating?
There is no guarantee that you will experience a clinical benefit from taking part in the study. Some of the procedures in this study, such as the recording of your weight, height and blood pressure present no risk to you. Other procedures, such as taking blood samples, can cause mild discomfort. The risks of taking a blood sample include slight discomfort when the needle is inserted and possible bruising and a localised infection. These procedures will only be carried out by experienced doctors under aseptic conditions to minimise all these risks.

Where is the study run from?
Imperial NIHR Clinical Research Facility, Hammersmith Hospital (UK)

When is the study starting and how long is it expected to run for?
March 2026 to July 2027

Who is funding the study?
The study is funded by King Faisal University through the Cultural Bureau of Saudi Arabia

Who is the main contact?
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Contact information

Type(s)
Principal investigator, Scientific, Public

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Integrated Research Application System (IRAS)
358173

Study information

Scientific Title
Gut microbial activity, lifestyle factors, and bone metabolism in premenopausal and postmenopausal women

Acronym
MENOGUT

Study objectives
To assess the impact of age-related lifestyle changes on SCFA levels and bone turnover markers in premenopausal and postmenopausal women

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 15/12/2025, London - Fulham Research Ethics Committee (2 Redman Place Stratford, London, E20 1JQ, United Kingdom; +44 (0)207 104 8241; fulham.rec@hra.nhs.uk), ref: 25/LO/0850

Primary study design
Observational

Secondary study design
Cross sectional study

Study type(s)

Health condition(s) or problem(s) studied
Osteoporosis

Interventions
A total of 42 participants will be recruited into the study, with 21 premenopausal women (aged 18–40 years) and 21 postmenopausal women (≥5 years post-menopause, aged 60 years and older). Each participant's involvement will be limited to one screening visit and one study visit. The total duration of the study is expected to be 36 months.

Visit 1 - Health Screening:
Participants will be recruited from the healthy volunteer database at the NIHR Imperial Clinical Research Facility. Potential participants will be identified based on a database search using the inclusion/exclusion criteria of the study. Identified individuals will be sent a letter that briefly describes the study. A contact number and email on the letter will enable potential participants to contact the research team at Imperial College. Participants will also be recruited from poster adverts placed around Imperial College London and Imperial NHS Trust sites. A contact number and email on the poster will enable potential participants to contact the research team at Imperial College.

These individuals will be invited to attend the NIHR Imperial Clinical Research Facility at Hammersmith Hospital, where their eligibility for the study will be assessed. Informed consent will be obtained. Individuals will have a blood test (HbA1c), and height and weight measurements will also be taken. Women of childbearing potential will complete a urinary pregnancy test. The screening visit will take approximately 1 hour.

Lifestyle behaviour measurements:
If eligible, participants will receive a wearable physical activity monitor (Alsamman et al., 2022), which will be worn continuously for 7 consecutive days on the wrist or waist using an adjustable strap. The device will objectively record physical activity levels, sedentary behaviour, sleep patterns, and heart rate.

Participants will also be asked to record their dietary intake over the same 7-day period using the Intake24 online dietary assessment tool (https://intake24.org/) (Foster et al., 2019). Additionally, they will be instructed to collect a stool sample during this period and bring it to the second visit for further analysis.

Visit 2:

The day prior to the study visit, the participants will be requested to refrain from strenuous exercise and alcohol. Participants will then be requested to fast overnight (they are allowed to drink water).

At approximately 09:00 participants will attend the NIHR Imperial Clinical Research Facility at Hammersmith Hospital. At approximately 09:30 fasting blood samples will be taken by venepuncture to measure bone metabolism markers (CTX-I, N-telopeptide of type I collagen (NTX-I, N-terminal propeptide of type I procollagen (PINP), osteocalcin, parathyroid hormone

and Vitamin D 25-hydroxy). NTX will also be measured in a spot urine sample. Lipopolysaccharide (LPS) levels will also be measured in blood samples as a marker of gut barrier function. A maximum of 20 ml of blood will be taken during the study visit.

Participants will be asked to provide a stool sample to assess SCFAs. Markers of gut barrier function (calprotectin and zonulin) will also be measured from stool samples. Participants will be provided with detailed instructions on how to do this and will be given appropriate containers. The study visit will take approximately 2 hours.

Intervention Type
Other

Primary outcome(s)
1. Faecal total short chain fatty acids measured using gas chromatography-mass spectrometry at Visit 2

Key secondary outcome(s)
1. Dietary fibre intake measured using 24 h food diaries at Visit 2

2. Physical activity levels measured using wearable physical activity monitor at Visit 2

3. Markers of bone turnover (CTX, NTX-I, PINP, Osteocalcin, PTH, Vitamin D) measured using enzyme-linked immunosorbent assays at Visit 2

4. Markers of gut permeability (plasma LPS and stool calprotectin and zonulin) measured using enzyme-linked immunosorbent assays at Visit 2

Completion date
01/07/2027

Eligibility

Key inclusion criteria
1. Premenopausal women aged 18-40 years
2. Postmenopausal women (≥5 years post menopause) aged 60 years and older
3. Healthy individuals without chronic diseases or conditions that significantly impact the gut microbiome, metabolism, or bone health (e.g., diabetes, inflammatory bowel disease, etc.)
4. HbA1c <48 mmol/mol
5. Individuals with a BMI between 18.5 and 30 kg/m² (normal weight to overweight)

Healthy volunteers allowed
Yes

Age group
Mixed

Lower age limit
18 Years

Upper age limit

100 Years

Sex
Female

Total final enrolment
0

Key exclusion criteria
1. Non-English speakers
2. Individuals with chronic diseases that affect the gut microbiome, metabolic health or bone metabolism (e.g. type 1 or 2 diabetes, bowel diseases such as Crohn's disease or irritable bowel syndrome, osteoporosis, etc)
3. HbA1c ≥48 mmol/mol
4. Individuals with a BMI less than 18.5 kg/m² (underweight) or greater than 30 kg/m² (obesity)
5. Medications and dietary supplements in the last 3 months that would impact trial outcomes:
5.1. Antibiotics
5.2. Proton Pump Inhibitors (PPIs)
5.3. Laxatives & Antidiarrheals
5.4. Immunosuppressants
5.5. Metformin
5.6. Nonsteroidal anti-inflammatory drugs
5.7. Bisphosphonates
5.8. Estrogen and/or progesterone (Hormone replacement therapy (HRT))
5.9. Denosumab
5.10. Anabolic steroids
5.11. Teriparatide
5.12. Thyroid medication
5.13. Dietary fibre, prebiotic or probiotic supplements
6. Known congenital or acquired bone disease other than osteopenia (including osteomalacia, hyperparathyroidism, Paget's disease)
7. History of major psychiatric illness
8. Drink more than 14 units of alcohol per week on a regular basis
9. Consumption of recreational drugs
10. Current smokers (daily)
11. Pregnancy
12. Not involved in other research projects in the previous 12 weeks

Date of first enrolment
01/03/2026

Date of final enrolment
28/02/2027

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

Funder Name
Saudi Arabian Cultural Bureau

Alternative Name(s)
The Saudi Arabian Cultural Bureau, SACB

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Saudi Arabia

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not expected to be made available