

# Presentation and clinical outcome of pregnancy-associated osteoporosis

<b>Submission date</b> 18/04/2022	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 17/01/2023	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 05/12/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Pregnancy-associated osteoporosis (PAO) is a rare condition that typically presents with multiple vertebral fractures during pregnancy or lactation. The cause of PAO is poorly understood. It is known that bone is normally lost from the maternal skeleton during pregnancy and lactation to meet the needs of the growing foetus and infant during breastfeeding, but the degree of bone loss is modest and very rarely results in clinically apparent osteoporosis. It has been speculated that individuals who develop PAO may have pre-existing osteoporosis which worsens during pregnancy as the result of physiological bone loss or may experience exaggerated bone loss for reasons that are unclear. The aim of this study is to document the characteristics of women who have been diagnosed with PAO, its clinical features and the mode of disease presentation. A specific aim will be to explore the possible role of genetic factors by gathering information on family history of osteoporosis and PAO and conducting genetic profiling. A control group will also volunteer to give a blood sample for genetic profiling. The longer-term objective of the study is to gain a greater understanding of why PAO occurs in the hope that this will improve clinical outcomes in patients with this rare but serious condition.

### Who can participate?

1. Women who have been diagnosed with Pregnancy Associated Osteoporosis (PAO)
2. Women known to the PAO cases who gave birth at around the same time and who were not diagnosed with PAO.

### What does the study involve?

Phase 1: Answering an online questionnaire to give details about the demographics, clinical features, quality of life and treatment histories of participants.

Phase 2: Patients who complete the questionnaire can give optional consent to be contacted to give blood samples for genetic analysis at their local hospital and to have their medical records searched for information pertaining to their diagnosis.

### What are the possible benefits and risks of participating?

There are no direct benefits to participants. There is a small risk of bruising during blood sampling.

Where is the study run from?

Institute of Genetics and Cancer, University of Edinburgh (UK)

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

January 2021 to June 2025

Who is funding the study?

Royal Osteoporosis Society (UK)

Who is the main contact?

Kathryn Berg

kathryn.berg@ed.ac.uk

## Contact information

### Type(s)

Scientific

### Contact name

Miss Kathryn Berg

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

287827

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

AC21004, IRAS 287827, CPMS 52578

## Study information

### Scientific Title

# Pregnancy Associated Osteoporosis Study

## Acronym

PAO

## Study objectives

The aim of this study is to document the demographics, clinical features, mode of presentation, genetic factors and treatment histories associated with the diagnosis of Pregnancy Associated Osteoporosis (PAO) to gain insight into the longer-term impact of the condition on bone health during subsequent pregnancies and later in life. A specific aim will be to explore the possible role of genetic factors on PAO by gathering information on family history of osteoporosis and PAO and by conducting genetic profiling to determine whether individuals with PAO have a specific genetic profile that might predispose them to the disease. The longer-term objective of the study is to gain a greater understanding of why PAO occurs in the hope that this will improve clinical outcome in patients with this rare but serious condition.

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 20/05/2021; London - Riverside Research Ethics Committee (Ground Floor, Temple Quay House, 2 The Square, Bristol, BS1 6PN, UK; +44 (0)2071048199; riverside.rec@hra.nhs.uk; ref: 21/PR/0608

## Study design

Observational cohort study

## Primary study design

Observational

## Secondary study design

Cohort study

## Study setting(s)

Hospital

## Study type(s)

Other

## Participant information sheet

See study outputs table

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

Pregnancy-associated osteoporosis

## Interventions

Phase 1:

The first phase of the study involves the completion of an online survey that asks its respondents for information about the diagnosis of their PAO; treatments taken, mode of diagnosis, symptoms at presentation, quality of life etc.

## Phase 2:

Participants can consent online to be contacted to take part in Phase 2 of the study. This involves having blood samples taken in their local hospital and consenting to have their medical records searched for more detailed information surrounding their diagnosis (e.g. bone density records).

## Intervention Type

Other

## Primary outcome measure

Bone mineral density change in relation to treatment received (if any), measured using dual-energy x-ray absorptiometry (DEXA) at all timepoints available after the initial diagnosis for up to 5 years

## Secondary outcome measures

1. Quality of life measured using SF36 at diagnosis recorded retrospectively at the time of answering the survey
2. Participant reported fracture number and type at diagnosis recorded retrospectively at the time of answering the survey
3. Validated fractures recorded on the participant's medical record at the original diagnosis and following the original diagnosis for up to 5 years
4. Recurrence of fractures during subsequent pregnancies as recorded on the participant's medical record at any timepoint

## Overall study start date

01/01/2021

## Completion date

30/06/2025

# Eligibility

## Key inclusion criteria

PAO cases:

1. Previously diagnosed with PAO
2. Willing and able to give informed consent

Controls:

1. Women known to a PAO participant who had a baby around the same time as a participant who was not diagnosed with PAO
2. Willing and able to give informed consent

## Participant type(s)

Healthy volunteer, Patient

## Age group

Adult

## Sex

Both

**Target number of participants**

250

**Key exclusion criteria**

Does not meet the inclusion criteria

**Date of first enrolment**

03/11/2021

**Date of final enrolment**

30/06/2024

**Locations****Countries of recruitment**

England

Scotland

United Kingdom

**Study participating centre****Western General Hospital**

Crewe Road South

Edinburgh

Lothian

United Kingdom

EH4 2XU

**Study participating centre****Queen Elizabeth University Hospital**

1345 Govan Road

Glasgow

United Kingdom

G51 4TF

**Study participating centre****Royal Liverpool University Hospital**

Prescot Street

Liverpool

United Kingdom

L7 8XP

# Sponsor information

## Organisation

Accord (United Kingdom)

## Sponsor details

47 Little France Crescent  
Edinburgh  
Scotland  
United Kingdom  
EH16 4TJ  
+44 (0)131 242 3330  
resgov@accord.scot

## Sponsor type

University/education

## Website

<http://accord.scot/>

## ROR

<https://ror.org/01x6s1m65>

# Funder(s)

## Funder type

Research organisation

## Funder Name

Royal Osteoporosis Society

## Alternative Name(s)

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Associations and societies (private and public)

## Location

United Kingdom

# Results and Publications

## Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal.

## Intention to publish date

01/07/2023

## Individual participant data (IPD) sharing plan

Participant level data will be held on secure servers at the Institute of Genetics and Cancer at the University of Edinburgh and will not be shared due to the rare nature of this disease and therefore the risk that a participant could be identified.

## IPD sharing plan summary

Not expected to be made available

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Participant information sheet</a>	Case version 4.0	13/09/2021	05/05/2022	No	Yes
<a href="#">Participant information sheet</a>	Control version 4.0	13/09/2021	05/05/2022	No	Yes
<a href="#">HRA research summary</a>			28/06/2023	No	No