

Presentation and clinical outcome of pregnancy-associated osteoporosis

Submission date 18/04/2022	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 17/01/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 25/09/2025	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data

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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

Integrated Research Application System (IRAS)

287827

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

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

Study type(s)

Other

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

225

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**

United Kingdom

England

Scotland

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)

ROR

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

Funder(s)

Funder type

Research organisation

Funder Name

Royal Osteoporosis Society

Alternative Name(s)

The Royal Osteoporosis Society (ROS), National Osteoporosis Society, ROS

Funding Body Type

Private sector organisation

Funding Body Subtype

Other non-profit organizations

Location

United Kingdom

Results and Publications

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?
Results article		12/09/2025	15/09/2025	Yes	No
HRA research summary			28/06/2023	No	No
Participant information sheet	Case version 4.0	13/09/2021	05/05/2022	No	Yes
Participant information sheet	Control version 4.0	13/09/2021	05/05/2022	No	Yes