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Pain in Paget's disease

Submission date	Recruitment status	[_] Prospectively registered
10/05/2021	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
14/06/2021	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
03/03/2025	Musculoskeletal Diseases	

Plain English summary of protocol

Background and study aims
Paget's disease of bone disrupts the normal cycle of bone renewal, causing bones to become weakened and possibly deformed. It's a fairly common condition in the UK, particularly in older people. It's rare in people under 50 years of age.
Bone pain is the most common symptom in patients with Paget's disease of bone (PDB), affecting around 73% of patients that come to clinical attention. However, the reason that pain occurs in some patients and not others is not understood. This study will look at a number of different potential factors, including: DNA and RNA analysis, the presence of markers of bone turnover in the blood, gut and mouth microbiomes, physical activity levels, diet, quality of life measures, and sensory testing.

Who can participate?
Anyone with a diagnosis of Paget's Disease of Bone who is over the age of 18 and is willing and able to comply and consent with the study protocol.

What does the study involve?
The study visit lasts approximately 90 minutes and involves blood samples being taken, questionnaires being answered and quantitative sensory testing being undertaken to compare sensory differences above affected and unaffected bone.

What are the possible benefits and risks of participating?
There are no direct benefits to participants themselves. There is a small risk of bruising during venepuncture.

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 2018 to December 2022

Who is funding the study?
The Paget's Association (UK)

Who is the main contact?
Kathryn Berg, kathryn.berg@ed.ac.uk

Contact information

Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
232314

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 232314, CPMS 41974

Study information

Scientific Title
Deciphering the mechanisms of pain in Paget's disease of bone

Acronym
PiP

Study objectives

The aim of this study is to document the frequency with which pain occurs and to explore the mechanisms of pain in a cohort study of up to 250 patients with PDB. The rationale for the study is to gain a greater understanding of why pain occurs in PDB and to identify biomarkers that might predict the occurrence or severity of pain.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/02/2019, West of Scotland Research Ethics Committee 3 (Clinical Research and Development, West Glasgow Ambulatory Care Hospital, Dalnair Street, Glasgow, G3 8SJ, UK; +44 (0)141 314 0211;
WoSREC3@ggc.scot.nhs.uk), ref: 18/WS/0236

Study design
Cross-sectional observational multi-centre study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
Paget's disease of bone (PDB)

Interventions
The study involves a single visit lasting approximately 90 minutes which involves blood samples being taken, questionnaires being answered and quantitative sensory testing being undertaken to compare sensory differences above affected and unaffected bone.

Intervention Type
Mixed

Primary outcome measure
Pain is measured using the BPI questionnaire and a visual analogue scale (VAS) at a single time point

Secondary outcome measures
QST will measure sensory detection and pain thresholds above affected and unaffected bone at a single time point

Overall study start date
01/01/2018

Completion date
31/12/2022

Eligibility

Key inclusion criteria
1. Clinical diagnosis of PDB
2. Age of 18 years or older
3. Willing and able to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
250

Total final enrolment
168

Key exclusion criteria
1. Unable to comply with study procedures.

Date of first enrolment
09/06/2019

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
England

Scotland

United Kingdom

Wales

Study participating centre
Western General Hospital
Crewe Road South
Edinburgh
United Kingdom
EH4 2XU

Study participating centre
Queen Elizabeth University Hospital
1345 Govan Road
Glasgow
United Kingdom
G51 4TF

Study participating centre
Newcastle Freeman Hospital
Freeman Rd
High Heaton
Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
The James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Royal Liverpool University Hospital
Prescot Street
Liverpool
United Kingdom
L7 8XP

Study participating centre

Salford Royal
Stott Lane
Salford
United Kingdom
M6 8HD

Study participating centre
Cardiff Royal Infirmary
Glossop Road
Cardiff
United Kingdom
CF24 0JT

Study participating centre
Manchester Royal Infirmary
Oxford Rd,
Manchester
United Kingdom
M13 9WL

Study participating centre
Norfolk & Norwich University Hospital
Colney Lane, Norwich, Norfolk
Norwich
United Kingdom
NR4 7UY

Study participating centre
Royal National Orthopaedic Hospital
Brockley Hill, Stanmore
London
United Kingdom
HA6 4LP

Study participating centre
Northern General Hospital
Herries Road
Sheffield
United Kingdom
S5 7AU

Study participating centre
Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre
Nottingham City Hospital
Hucknall Road
Nottingham
United Kingdom
NG5 1PB

Sponsor information

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Accord (United Kingdom)

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Sponsor type
University/education

Website
http://accord.scot/

ROR
https://ror.org/01x6s1m65

Funder(s)

Funder type
Charity

Funder Name
Paget's Association

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal.

Intention to publish date
01/12/2023

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request (Kathryn Berg, kathryn.berg@ed.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 v4.0	05/04/2019	14/06/2021	No	Yes
Protocol file	version v5.0	09/07/2019	14/06/2021	No	No
HRA research summary			28/06/2023	No	No
Results article		30/09/2024	03/03/2025	Yes	No