

Multi-centre randomised controlled trial of symptomatic versus intensive bisphosphonate therapy for Paget's disease

Submission date 05/02/2002	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 05/02/2002	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/12/2023	Condition category Musculoskeletal Diseases	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data

Plain English summary of protocol

Not provided at time of registration

Study website

<http://www.abdn.ac.uk/hsru/hta/prism.shtml>

Contact information

Type(s)

Scientific

Contact name

Prof SH Ralston

Contact details

University of Edinburgh, Molecular Medicine Centre
Western General Hospital
Crewe Road South
Edinburgh
United Kingdom
EH4 2XU
+44 (0)131 651 1037 / 1035
stuart.ralston@ed.ac.uk

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

ARC 13627

Study information

Scientific Title

Multi-centre randomised controlled trial of symptomatic versus intensive bisphosphonate therapy for Paget's disease

Acronym

PRISM

Study objectives

Intensive bisphosphonate therapy is superior to symptomatic management in the prevention of long-term complications associated with Paget's disease of bone

Ethics approval required

Old ethics approval format

Ethics approval(s)

Not provided at time of registration

Study design

Multicentre randomised controlled trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Paget's disease

Interventions

Patients will be randomised to either symptomatic treatment or intensive treatment with a bisphosphonate to maintain serum alkaline phosphatase within the normal range

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Bisphosphonate

Primary outcome measure

Fracture rate

Secondary outcome measures

1. Progression of hearing loss
2. Self-reported health related quality of life
3. Requirement for joint replacement

Overall study start date

01/12/2001

Completion date

31/12/2010

Eligibility

Key inclusion criteria

The trial will involve patients with Paget's disease over the age of 18 years with symptomatic or asymptomatic disease receiving care at participating hospitals throughout the UK.

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

1300

Total final enrolment

1324

Key exclusion criteria

1. Under 18 years of age
2. Unable to provide written consent
3. Judged by clinician to be too ill or frail to participate
4. Life expectancy of less than one year

Date of first enrolment

01/12/2001

Date of final enrolment

31/12/2010

Locations

Countries of recruitment

Scotland

United Kingdom

Study participating centre

University of Edinburgh, Molecular Medicine Centre

Edinburgh

United Kingdom

EH4 2XU

Sponsor information

Organisation

University of Edinburgh and NHS Lothian (UK)

Sponsor details

Queen's Medical Research Institute

Room E1:06

47 Little France Crescent

Edinburgh

United Kingdom

EH16 4TJ

+44 (0)131 242 9262

marise.bucukoglu@ed.ac.uk

Sponsor type

Government

ROR

<https://ror.org/03q82t418>

Funder(s)

Funder type

Charity

Funder Name

Arthritis UK (previously Arthritis Research Campaign [ARC]) (UK)

Funder Name

Aventis & Procter & Gamble (UK)

Funder Name

National Association for Relief of Paget's Disease (NARPD) (UK)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/01/2010		Yes	No
Other publications	Genetic analysis of PRISM participants	01/11/2010	21/12/2023	Yes	No