ISRCTN12989577 https://doi.org/10.1186/ISRCTN12989577

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

Registration date
05/02/2002

Overall study status
Completed

Last Edited
21/12/2023

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol
Not provided at time of registration

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

Protocol serial number
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

Study type(s)
Treatment

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(s)
Fracture rate

Key secondary outcome(s))
1. Progression of hearing loss
2. Self-reported health related quality of life
3. Requirement for joint replacement

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

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
United Kingdom

Scotland

Study participating centre
University of Edinburgh, Molecular Medicine Centre
Edinburgh

United Kingdom
EH4 2XU

Sponsor information

Organisation
University of Edinburgh and NHS Lothian (UK)

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

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

Study website	Study website	11/11/2025	11/11/2025	No	Yes