ISRCTN15928978 https://doi.org/10.1186/ISRCTN15928978

An international study to assess the effects of strontium ranelate in the reduction of bone loss around the metal implant, in patients with hip prosthesis

Submission date
31/05/2011

Recruitment status
No longer recruiting

Registration date
04/08/2011

Overall study status
Completed

Last Edited
21/04/2020

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 and not expected to be available in the future

Contact information

Type(s)
Scientific

Contact name
Prof Maria Luisa Brandi

Contact details
AOUC-D.A.I Ortopedia S.O.D
Malattie del Metabolismo Minerale ed Osseo CTO
Azienda Ospedaliero
Universitaria CareggiLargo Pelagi 1
Firenze
Italy
50139

Additional identifiers

Clinical Trials Information System (CTIS)
2010-020215-36

Protocol serial number
CL3-12911-037

Study information

Scientific Title
A prospective, controlled, double blind, international study to assess the effects of strontium ranelate vs placebo on the reduction of periprosthetic bone loss in patients with total hip arthroplasty

Study objectives
To demonstrate the efficacy of strontium ranelate in the reduction of bone loss in patients with total hip arthroplasty

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Prospective placebo-controlled randomised double-blind study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Periprosthetic bone loss / total hip arthroplasty

Interventions
Intervention (63 paticipants) - One sachet of 2g of strontium ranelate daily
Placebo (63 paticipants)
Total duration of intervention is 12 months.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Strontium ranelate

Primary outcome(s)
The relative change of periprosthetic bone mineral density (BMD) in region 7 of Gruen after total hip arthroplasty over 12 months

Key secondary outcome(s))
1. The relative change of other regions of Gruen over 12 months
2. Safety over 12 months

Completion date
30/04/2013

Eligibility

Key inclusion criteria
1. Caucasian male or postmenopausal women
2. Age less than or equal to 50 years
3. Patients with conventional primary total hip arthroplasty, cementless femoral stem and primary coxarthrosis as indication for total hip arthroplasty

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Total final enrolment
96

Key exclusion criteria
1. Short femoral stem
2. Any perioperative complication
3. Patient with inflammatory arthropathy
4. Impossibility to perform Dual-emission X-ray absorptiometry (DXA)
5. Increase risk or history of venous thromboembolism (VTE)
6. Known hypersensitivity or contraindication to the study drug or Calperos D3®
7. Concomittant treatments likely to interfere with bone metabolism

Date of first enrolment
01/05/2011

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
Belgium

Brazil

Germany

Italy

Spain

Study participating centre
AOUC-D.A.I Ortopedia S.O.D
Firenze
Italy
50139

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request from https://clinicaltrials.servier.com if a Marketing Authorisation has been granted after 1st January 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Basic results			21/04/2020	No	No

Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes