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

EudraCT/CTIS number
2010-020215-36

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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

Secondary outcome measures
1. The relative change of other regions of Gruen over 12 months
2. Safety over 12 months

Overall study start date
01/05/2011

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

Age group
Adult

Sex
Both

Target number of participants
126

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)

Sponsor details
50 rue Carnot
Suresnes
France
92284

Sponsor type
Industry

Website
http://www.servier.com/

ROR
https://ror.org/034e7c066

Funder(s)

Funder type
Industry

Funder Name
Institut de Recherches Internationales Servier (France)

Results and Publications

Publication and dissemination plan
Publication plan:
Summary results are published on https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

Intention to publish date

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