

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	<input type="checkbox"/> Prospectively registered
Registration date 04/08/2011	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 21/04/2020	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 and not expected to be available in the future

Contact information

Type(s)

Scientific

Contact name

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Contact details

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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 participants) - One sachet of 2g of strontium ranelate daily

Placebo (63 participants)

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