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 | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------------------|--|-----------------------------|--|--|
| 31/05/2011 | | ☐ Protocol | | |
| Registration date 04/08/2011 | Overall study status Completed | Statistical analysis plan | | |
| | | [X] Results | | |
| Last Edited 21/04/2020 | Condition category Musculoskeletal Diseases | Individual participant data | | |
| Z 1/U4/ZUZU | MUSCUIOSKEIELAI DISEASES | | | |

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 |