

Long-term effects of strontium ranelate on knee osteoarthritis symptoms: a two year prospective, randomised, placebo-controlled study

Submission date 29/09/2006	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 12/10/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/03/2018	Condition category Musculoskeletal Diseases	<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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Liège
Belgium
4020

Additional identifiers

Protocol serial number

CL3-12911-028

Study information

Scientific Title

Long-term effects of strontium ranelate on knee osteoarthritis symptoms. A 2-year prospective, randomised, placebo-controlled study.

Study objectives

To assess the effectiveness on algofunctional symptoms of knee osteoarthritis.

Please note that as of 27/11/2012, the anticipated end date was updated from 30/06/2009 to 30/12/2009

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee approval obtained on 07/09/2006 (n° 154): Comité d'Ethique Hospitalo-Facultaire Universitaire de Liège.

Study design

Randomised, double-blind, parallel-group, placebo-controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Osteoarthritis

Interventions

Strontium ranelate versus placebo.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Strontium ranelate

Primary outcome(s)

Changes in the algofunctional behaviour of the target knee.

Key secondary outcome(s)

1. Algofunctional assessment
2. Radiographic assessment of knee osteoarthritis
3. Physical examination

Completion date

30/12/2009

Eligibility

Key inclusion criteria

1. Caucasian males or females
2. Aged 45 years or over
3. Primary knee osteoarthritis
4. Under an effective contraceptive method for non-menopausal women

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Knee prosthesis already implanted, or foreseen to be implanted
2. Hip prosthesis already implanted or not well-tolerated or foreseen to be implanted
3. Previous osteotomy on the inferior limbs

Date of first enrolment

30/11/2006

Date of final enrolment

30/12/2009

Locations**Countries of recruitment**

Belgium

Study participating centre

Policlinique Brull, 45 Quai Godefroid Kurth

Liège

Belgium

4020

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