

The efficacy and safety of strontium ranelate versus placebo in the treatment of knee osteoarthritis

Submission date 11/03/2010	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 14/04/2010	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 28/03/2018	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

Study information

Scientific Title

The efficacy and safety of two doses of strontium ranelate versus placebo administered orally for 3 years in the treatment of knee osteoarthritis: a prospective multicentre, international, double-blind, placebo-controlled study

Study objectives

To demonstrate the superiority of strontium ranelate versus placebo against articular cartilage damage progression over three years in men and women with knee osteoarthritis.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

Study design

Randomised double-blind parallel-group placebo-controlled trial

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

Osteoarthritis

Interventions

The treatment is composed of two doses of strontium ranelate (1 g and 2 g per day) administered orally for 3 years.

Intervention Type

Drug

Phase

Phase III

Drug/device/biological/vaccine name(s)

Strontium ranelate

Primary outcome measure

Radiographic assessment of knee osteoarthritis measured up to 36 months

Secondary outcome measures

Measured up to 36 months:

1. Algofunctional assessment
2. Physical examination
3. Safety

Overall study start date

30/06/2008

Completion date

30/04/2013

Eligibility

Key inclusion criteria

1. Asia men and women of at least 50 years of age
2. Primary knee osteoarthritis

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

450

Key exclusion criteria

1. Knee prosthesis already implanted or foreseen within the next year
2. Hip prosthesis recently implanted (less than 1 year) or not well-tolerated, or foreseen within the next year

Date of first enrolment

30/06/2008

Date of final enrolment

30/04/2013

Locations

Countries of recruitment

China

Korea, South

Taiwan

Study participating centre

Rheumatology and Clinical Immunology Division

Beijing

China

100730

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

Summary results are published on <https://clinicaltrials.servier.com/>.

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