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

Submission date	Recruitment status	[ ] Prospectively registered
11/03/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
14/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/03/2018	Musculoskeletal 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

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-12911-022

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