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

Submission date	Recruitment status  No longer recruiting	<ul><li>Prospectively registered</li></ul>		
11/03/2010		∐ Protocol		
Registration date	Overall study status Completed	Statistical analysis plan		
14/04/2010		[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

#### Contact name

Prof Feng Chun Zhang

#### Contact details

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## Additional identifiers

Protocol serial number

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

#### Study type(s)

Treatment

#### 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(s)

Radiographic assessment of knee osteoarthritis measured up to 36 months

## Key secondary outcome(s))

Measured up to 36 months:

- 1. Algofunctional assessment
- 2. Physical examination
- 3. Safety

#### 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** 

#### Healthy volunteers allowed

No

#### Age group

Adult

#### Sex

All

#### 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)

#### **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
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes