ISRCTN41323372 https://doi.org/10.1186/ISRCTN41323372

# The efficacy and safety of two doses of strontium ranelate versus placebo, administered orally for three years in the treatment of knee osteoarthritis

**Submission date**
05/05/2006

**Registration date**
13/06/2006

**Last Edited**
18/04/2018

**Recruitment status**
No longer recruiting

**Overall study status**
Completed

**Condition category**
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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**
Prof Cyrus Cooper

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## Additional identifiers

**Clinical Trials Information System (CTIS)**
2005-002494-75

**Protocol serial number**
CL3-12911-018

## Study information

## Scientific Title
The efficacy and safety of two doses of strontium ranelate (1g and 2g per day) 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

Please note, as of 01/03/2011 the following updates have been made to this record:
1. The anticipated end date for this trial has been moved from 15/04/2009 to 30/03/2011
2. The public title has been updated. The previous title was 'The efficacy and safety of two doses of strontium ranelate versus placebo, administered orally for two years in the treatment of knee osteoarthritis. A prospective multicentre, international, double-blind, placebo-controlled study'.
3. The study hypothesis has been updated. The previous hypothesis was 'To demonstrate the superiority of strontium ranelate versus placebo against articular cartilage damage progression over two years in men and women with knee osteoarthritis'.
4. The target number of participants has been increased from 960 to 1680.

## Ethics approval required
Old ethics approval format

## Ethics approval(s)
First ethics committee approval given by the Ethical Committee of the Ospitalieri Institute of Verona on 14/12/2005, reference number: 1260)

## Study design
Prospective multicentre international double-blind placebo-controlled study

## 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)
Radiographic assessment of knee osteoarthritis

### Key secondary outcome(s))
1. Algofunctional assessment
2. Physical examination
3. Safety

### Completion date
30/03/2011

## Eligibility

### Key inclusion criteria
1. Caucasian men and women of at least 50 years of age
2. Primary knee osteoarthritis
3. Under 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 within the next year
2. Hip prosthesis recently implanted (<1 year) or not well-tolerated, or foreseen within the next year

### Date of first enrolment
15/04/2006

### Date of final enrolment
30/03/2011

## Locations

### Countries of recruitment
United Kingdom

England

Australia

Austria

Belgium

Canada

Czech Republic

Denmark

Estonia

France

Germany

Italy

Lithuania

Netherlands

Poland

Portugal

Romania

Russian Federation

Spain

**Study participating centre**
**University of Southampton**
Southampton
United Kingdom
SO16 6YD

# 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 2014.

### IPD sharing plan summary
Available on request

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Results article | results | 01/02/2013 | | Yes | No |
| Results article | results | 01/08/2014 | | Yes | No |
| Results article | results | 01/02/2015 | | Yes | No |
| Basic results | | | | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |