

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	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 13/06/2006	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 18/04/2018	Condition category Musculoskeletal Diseases	☐ 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

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)

Primary study design

Interventional

Study design

Prospective multicentre international double-blind placebo-controlled study

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
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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