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	Recruitment status	Prospectively registered
05/05/2006	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
13/06/2006	Completed	[X] Results
Last Edited	Condition category	Individual participant data
18/04/2018	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 Cyrus Cooper

Contact details

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Additional identifiers

EudraCT/CTIS number 2005-002494-75

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

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

Strontium ranelate versus placebo

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Strontium ranelate

Primary outcome measure

Radiographic assessment of knee osteoarthritis

Secondary outcome measures

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

Overall study start date

15/04/2006

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

Age group

Adult

Sex

Both

Target number of participants

Added 01/03/2011: 1680 (960 at time of registration)

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 Australia Austria Belgium Canada Czech Republic Denmark England Estonia France Germany Italy Lithuania Netherlands Poland Portugal Romania Russian Federation

United Kingdom

Spain

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

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

Current version as of 28/03/2018:

Summary results are published in https://clinicaltrials.servier.com.

For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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.

Previous version as of 24/01/2018:

Publication plan:

All phases - Interventional studies ending before 01/10/2018: Summary results will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.

All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.

Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

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 2014.

IPD sharing plan summary

Available on request

Study outputs

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