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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

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Additional identifiers

EudraCT/CTIS number
2005-002494-75

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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

Spain

United Kingdom

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	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	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