ISRCTN49960746 https://doi.org/10.1186/ISRCTN49960746

The efficacy and safety of strontium ranelate in the treatment of male osteoporosis: a prospective multicentre, international, double-blind, placebo-controlled study with a treatment duration of 2 years and the main study analysis after 1 year

Submission date
18/10/2007

Recruitment status
No longer recruiting

Registration date
30/11/2007

Overall study status
Completed

Last Edited
28/03/2018

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
2006-006086-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-12911-032

Study information

Scientific Title
The efficacy and safety of 2g strontium ranelate in the treatment of male osteoporosis. A prospective multicentre, international, double-blind, placebo-controlled study with a treatment duration of 2 years and the main study analysis after 1 year. - MALEO

Acronym
MALEO

Study objectives
To demonstrate the efficacy over 1 year of strontium ranelate compared to placebo on lumbar Bone Mineral Density (BMD) in men with osteoporosis.

As of 01/03/2011 the anticipated end date for this trial has been updated from 15/10/2009 to 28 /02/2011

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from local medical ethics committee in Italy on 13/09/2007

Study design
Randomised, double-blind, 2 parallel group, placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
Male osteoporosis

Interventions
Strontium ranelate versus placebo for two years.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Strontium ranelate

Primary outcome measure
Bone Mineral Density (BMD) of the lumbar spine.

Primary and secondary outcomes will be measured every 6 months.

Secondary outcome measures
1. BMD at the hip
2. Biochemical bone markers

Primary and secondary outcomes will be measured every 6 months.

Overall study start date
15/10/2007

Completion date
28/02/2011

Eligibility

Key inclusion criteria
1. Caucasian males of at least 65 years of age
2. Osteoporosis

Participant type(s)
Patient

Age group
Senior

Sex
Male

Target number of participants
221

Key exclusion criteria

1. BMD T-score less than -4.0
2. More than two prevalent mild and/or moderate osteoporotic vertebral fractures
3. Severe osteoporotic vertebral fractures

Date of first enrolment
15/10/2007

Date of final enrolment
28/02/2011

Locations

Countries of recruitment
Australia

Belgium

Canada

France

Germany

Hungary

Ireland

Italy

Netherlands

Poland

Russian Federation

South Africa

Spain

Sweden

United Kingdom

Study participating centre
U.Z GENT Polyclinique dEndocrinologie
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Belgium
9000

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
Summary results are published on https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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 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
Results article	results	01/02/2013		Yes	No