

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

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|--|---|--|
| Submission date 18/10/2007 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 30/11/2007 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 28/03/2018 | Condition category Musculoskeletal Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> 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

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

Gent

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 |