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

| Submission date | Recruitment status No longer recruiting | Prospectively registered | | |
|-------------------|--|--|--|--|
| 18/10/2007 | | ☐ Protocol | | |
| Registration date | Overall study status Completed | Statistical analysis plan | | |
| 30/11/2007 | | [X] Results | | |
| Last Edited | Condition category | Individual participant data | | |
| 28/03/2018 | 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 J.M. Kaufman

Contact details

U.Z GENT Polyclinique dEndocrinologie De Pintelaan 185 Gent Belgium 9000

Additional identifiers

Clinical Trials Information System (CTIS) 2006-006086-16

Protocol serial number

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

Study type(s)

Treatment

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(s)

Bone Mineral Density (BMD) of the lumbar spine.

Primary and secondary outcomes will be measured every 6 months.

Key secondary outcome(s))

- 1. BMD at the hip
- 2. Biochemical bone markers

Primary and secondary outcomes will be measured every 6 months.

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

Healthy volunteers allowed

No

Age group

Senior

Sex

Male

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

United Kingdom

Australia

Belgium

| Sweden | | | | | |
|--|--|--|--|--|--|
| Study participating centre U.Z GENT Polyclinique dEndocrinologie Gent Belgium 9000 | | | | | |
| Sponsor information | | | | | |
| Organisation Institut de Recherches Internationales Servier (France) | | | | | |
| ROR https://ror.org/034e7c066 | | | | | |
| Funder(s) | | | | | |

Canada

France

Germany

Hungary

Ireland

Poland

Spain

Netherlands

South Africa

Funder type Industry

Russian Federation

Italy

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 1st January 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 |
| Basic results | | | No | No |
| Participant information sheet | Participant information sheet | 11/11/2025 11/11/2025 | No | Yes |