

A double-blind, multicentric, multinational randomised study to assess the effects of two years administration of 2 g per day of strontium ranelate versus bisphosphonate in women with postmenopausal osteoporosis on bone geometry and bone strength measured by peripheral-Quantitative Computed Tomography (p-QCT)

Submission date 28/08/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 17/09/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 28/03/2018	Condition category Musculoskeletal Diseases	<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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Additional identifiers

Clinical Trials Information System (CTIS)

2007-001509-11

Protocol serial number

CL3-12911-030

Study information

Scientific Title

A double-blind, multicentric, multinational randomised study to assess the effects of two years administration of 2 g per day of strontium ranelate versus alendronate 70 mg per week in women with postmenopausal osteoporosis on bone geometry and bone strength measured by peripheral-Quantitative Computed Tomography (p-QCT).

Study objectives

Current hypothesis as of 03/03/2011:

To assess the effects of strontium ranelate in comparison with bisphosphonate on cortical thickness, the bone geometrical parameters and bone strength in patients with postmenopausal osteoporosis

Previous hypothesis:

To assess the effects of strontium ranelate in comparison with bisphosphonate on the bone geometry and bone strength in patients with postmenopausal osteoporosis.

Please note, as of 01/03/2011 the following updates have been made to this record:

- The anticipated end date has been updated from 30/09/2010 to 30/03/2011.
- The target number of participants has been increased from 80 to 148.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval was obtained before recruitment of the first participants

Study design

Randomised double-blind double-dummy trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Post-menopausal osteoporosis

Interventions

2 g strontium ranelate versus bisphosphonate for two years.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Strontium ranelate, bisphosphonate

Primary outcome(s)

Current primary outcome measure(s) as of 01/03/2011:

Cortical thickness measured every 6 months from baseline to M024

Previous primary outcomes measure(s):

Geometrical and bone strength parameters, measured at baseline and 2 years.

Key secondary outcome(s)

Current secondary outcome measure(s) as of 01/03/2011:

1. Geometrical and bone strength parameters
2. Bone Mineral Density (BMD)
3. Bone markers

Main secondary outcome measure timepoints are at baseline, M012, M024

Previous secondary outcome measures(s):

1. Bone content
2. Bone density
3. Bone Mineral Density (BMD)
4. Bone markers

Main secondary outcome measure timepoints are at baseline and 2 years.

Completion date

30/03/2011

Eligibility

Key inclusion criteria

1. Women of at least 50 years old
2. Post-menopausal for at least 5 years
3. Osteoporosis

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Evolutive cancer during the past 5 years with a risk of bone metastases
2. Body Mass Index less than 18 or greater than 30 kg/m²
3. Severe malabsorption

Date of first enrolment

30/09/2007

Date of final enrolment

30/03/2011

Locations**Countries of recruitment**

Belgium

Germany

Greece

Italy

Sweden

Study participating centre

Charité Campus Benjamin Franklin

Berlin

Belgium

D-12203

Sponsor information**Organisation**

Institut de Recherches Internationales Servier (France)

ROR

<https://ror.org/034e7c066>

Funder(s)

Funder type

Industry

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	01/08/2010		Yes	No
Basic results				No	No