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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	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 17/09/2007	**Overall study status** Completed	
Last Edited 28/03/2018	**Condition category** 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

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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 bisphophonate 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/m^2
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