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A double-blind, multicentric, multinational randomised study to assess the effects of one year administration of 2 g per day of strontium ranelate versus marketed bisphosphonates in women with postmenopausal osteoporosis on bone microarchitecture as measured by high-resolution peripheral-quantitative computed tomography (p-QCT)

Submission date
03/03/2006

Registration date
31/03/2006

Last Edited
18/04/2018

Recruitment status
No longer recruiting

Overall study status
Completed

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

Clinical Trials Information System (CTIS)
2006-002732-22

Protocol serial number
CL3-12911-019

Study information

Scientific Title
A double-blind, multicentric, multinational randomised study to assess the effects of one year administration of 2 g per day of strontium ranelate versus marketed bisphosphonates in women with postmenopausal osteoporosis on bone microarchitecture as measured by high-resolution peripheral-quantitative computed tomography (p-QCT)

Study objectives
To demonstrate the effects of strontium ranelate on bone microarchitecture in women with postmenopausal osteoporosis in comparison with marketed bisphosphonates.

On 27/11/2012 the anticipated end date for this trial was updated from 31/10/2007 to 28/02/2008.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Ethics Committee approval obtained on 21/09/2005 in France, ref: 2005-064-2

Study design
Double-blind randomised controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Post-menopausal osteoporosis

Interventions
Strontium ranelate (S12911) versus marketed bisphosphonates.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Bisphosphonates, strontium ranelate

Primary outcome(s)
Assessment of trabecular bone volume to tissue volume

Key secondary outcome(s))
Assessment of bone density, bone structure and bone markers

Completion date
28/02/2008

Eligibility

Key inclusion criteria
1. Women of at least 50 years old
2. Postmenopausal for at least five years
3. Osteoporosis

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
1. Body mass index (BMI) <18 or >30 kg/m^2
2. Skeletal disease
3. Severe malabsorption
4. Significant and evolutive hyperthyroidism

Date of first enrolment
31/10/2005

Date of final enrolment
28/02/2008

Locations

Countries of recruitment
Australia

France

Germany

Switzerland

Study participating centre
Hôpital Cantonal de Genève
Geneve 14
Switzerland
1211

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 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