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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

Contact name
Prof René Rizzoli

Contact details
Hôpital Cantonal de Genève
Département de Réhabilitation et Gériatrie
Service des Maladies Osseuses
24, Rue Michelidu-Crest
Geneve 14
Switzerland
1211

Additional identifiers

EudraCT/CTIS number
2006-002732-22

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

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
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 measure
Assessment of trabecular bone volume to tissue volume

Secondary outcome measures
Assessment of bone density, bone structure and bone markers

Overall study start date
31/10/2005

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

Age group
Adult

Sex
Female

Target number of participants
72

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)

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
Current version as of 28/03/2018:
Summary results are published in https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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.

Previous version as of 24/01/2018:
Publication plan:
All phases - Interventional studies ending before 01/10/2018: Summary results will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

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 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results	results			No	No

Results article	01/08/2010	Yes	No