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A double-blind, multicentre, international randomised study to assess the effects of 6 months or 12 months administration of strontium ranelate versus biphosphonates on bone remodelling and bone safety assessed by histomorphometry in women with postmenopausal osteoporosis

Submission date
04/06/2007

Recruitment status
No longer recruiting

Registration date
12/07/2007

Overall study status
Completed

Last Edited
20/04/2020

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

EudraCT/CTIS number

2006-005581-39

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-12911-025

Study information

Scientific Title
A double-blind, multicentre, international randomised study to assess the effects of 6 months or 12 months administration of strontium ranelate versus biphosphonates on bone remodelling and bone safety assessed by histomorphometry in women with postmenopausal osteoporosis

Study objectives
To assess the effects of 6 or 12 months treatment of strontium ranelate in comparison with biphosphonates on bone formation assessed by histomorphometry on transiliac paired biopsies performed in patients with postmenopausal osteoporosis treated for one year.

Ethics approval required
Old ethics approval format

Ethics approval(s)
First Ethics Committee approval obtained on 01/03/2007 in Milan, Italy (ref: 148)

Study design
Double-blind double-dummy 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
Postmenopausal osteoporosis in women

Interventions

Intervention group: 2 g (one sachet) orally per day of strontium ranelate and one capsule of placebo for 6 or 12 months
Control group: one capsule of bisphosphonates and one sachet of placebo for 6 or 12 months

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Histomorphometry on paired transiliac biopsies performed at baseline and after treatment (cancellous mineralising surfaces).

Secondary outcome measures
1. Other histomorphometric parameters
2. Bone markers

Overall study start date
01/06/2007

Completion date
31/12/2009

Eligibility

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

Participant type(s)
Patient

Age group
Adult

Sex
Female

Target number of participants
285

Total final enrolment
387

Key exclusion criteria

1. Any medical or anatomical condition that potentially could put the patient at additional risk of an adverse event due to the biopsy procedure or that potentially could lead to an impossibility to perform a transiliac bone biopsy on each side
2. Previous and concomitant treatments interfering with bone metabolism

Date of first enrolment
01/06/2007

Date of final enrolment
31/12/2009

Locations

Countries of recruitment
Argentina

Australia

Belgium

Brazil

Canada

Czech Republic

Denmark

Estonia

France

Hungary

Italy

Mexico

Poland

United Kingdom

Study participating centre
INSERM Unité 831
Lyon
France
69437

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
Publication plan:
Summary results are published on https://clinicaltrials.servier.com/.

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 1st January 2014.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Basic results				No	No
Basic results			20/04/2020	No	No