

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	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 12/07/2007	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 20/04/2020	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

Prof Pierre D. Delmas

Contact details

INSERM Unité 831
Service de Rhumatologie et de Pathologie Osseuse Pavillon F
Hôpital E. Herriot
Lyon
France
69437

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