

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

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Additional identifiers

Clinical Trials Information System (CTIS)

2006-005581-39

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

1. Other histomorphometric parameters
2. Bone markers

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

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

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**

United Kingdom

Argentina

Australia

Belgium

Brazil

Canada

Czech Republic

Denmark

Estonia

France

Hungary

Italy

Mexico

Poland

Study participating centre

INSERM Unité 831

Lyon

France

69437

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?
Basic results				No	No
Basic results			20/04/2020	No	No