

# Efficacy and safety of strontium ranelate /vitamin D3 combination on vitamin D deficiency in the treatment of osteoporotic patient

<b>Submission date</b> 20/05/2010	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/06/2010	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 20/04/2020	<b>Condition category</b> 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

Prof Rene Rizzoli

### Contact details

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Hôpital Cantonal  
Genève 14  
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## Additional identifiers

### Clinical Trials Information System (CTIS)

2009-014270-18

### Protocol serial number

CL3-06911-003

## Study information

**Scientific Title**

The efficacy and safety of a daily oral administration of S06911 (strontium ranelate 2g/vitamin D3 1000 IU fixed combination) on vitamin D deficiency in the treatment of osteoporotic postmenopausal women and men. A 12 month, prospective, open labelled, one treatment group international phase III study.

**Study objectives**

To demonstrate the efficacy and the safety of S06911 in patients with vitamin D deficiency.

Please note that as of 27/11/2012, the following changes were made to the record:

1. Denmark was removed from the countries of recruitment
2. The anticipated end date was updated from 27/07/2011 to 30/06/2011

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics approval was obtained before recruitment of the first participants

**Study design**

Prospective open-labelled phase III study

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Osteoporosis, vitamin D deficiency

**Interventions**

One sachet per day of strontium ranelate/vitamin D3 fixed combination during 12 months.

**Intervention Type**

Supplement

**Phase**

Phase III

**Drug/device/biological/vaccine name(s)**

Strontium ranelate/vitamin D3 combination (S06911)

**Primary outcome(s)**

Evaluate the efficacy over 12 months of treatment on the correction of vitamin D insufficiency in patients with deficient vitamin D serum levels

**Key secondary outcome(s)**

1. Evaluate the efficacy over 12 months of treatment on the correction of vitamin D deficiency
2. Safety evaluation each 3 months

**Completion date**

30/06/2011

## Eligibility

**Key inclusion criteria**

1. Osteoporotic men and osteoporotic post-menopausal women
2. Age superior or equal 50 years
3. Caucasian
4. 25-OH vitamin D3 serum concentration inferior or equal to 22.5 nmol/L

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**Total final enrolment**

19

**Key exclusion criteria**

1. Progressive major illness
2. Uncontrolled active disease
3. Skeletal disease
4. History or increased risk of deep venous thrombosis or pulmonary embolism
5. History of intolerance, allergy or severe hypersensitivity with study drugs

**Date of first enrolment**

27/01/2010

**Date of final enrolment**

30/06/2011

## Locations

**Countries of recruitment**

Belgium

Poland

Russian Federation

Slovakia

Spain

Switzerland

### Study participating centre

Département de réhabilitation et gériatrie

Genève 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?
<a href="#">Basic results</a>				No	No
<a href="#">Basic results</a>			20/04/2020	No	No