

# **SOTI and TROPOS phase III studies open-label extension. The long term efficacy and long term safety assessment of a five-year oral administration of strontium ranelate in osteoporotic postmenopausal women having participated either in Spinal Osteoporosis Therapeutic Intervention "SOTI" study or Treatment Of Peripheral Osteoporosis "TROPOS" study. A five-year multicentric multinational open study with strontium ranelate.**

<b>Submission date</b> 05/09/2007	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 16/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 18/04/2018	<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**  
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## **Additional identifiers**

### **Protocol serial number**

CL3-12911-012

## **Study information**

### **Scientific Title**

SOTI and TROPOS phase III studies open-label extension. The long term efficacy and long term safety assessment of a five-year oral administration of strontium ranelate in osteoporotic postmenopausal women having participated either in Spinal Osteoporosis Therapeutic Intervention "SOTI" study or TRreatment Of Peripheral Osteoporosis "TROPOS" study. A five-year multicentric multinational open study with strontium ranelate.

### **Study objectives**

1. To assess the efficacy of an additional 5-year oral administration of strontium ranelate on bone mineral density (BMD), on the number of patients experiencing new osteoporotic fractures on body height and on bone markers in the SOTI and TROPOS patients having already received active treatment for 4 or 5 years
2. To allow patients treated with placebo in the main part of the SOTI study or for 5 years in the TROPOS study to receive active treatment for a duration known to be effective on vertebral fractures
3. To assess the safety of an additional 5-year oral administration of strontium ranelate in SOTI and TROPOS patients having already received active treatment for 4 or 5 years
4. To assess the safety of a 5-year oral administration of strontium ranelate in SOTI and TROPOS patients treated with placebo in the main part of the SOTI or TROPOS studies

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

Ethics approval was obtained before recruitment of the first participants

### **Study design**

Open international multicentric study

### **Primary study design**

Interventional

### **Study type(s)**

Not Specified

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

Postmenopausal osteoporosis

## **Interventions**

All participants will take 2 g per day of strontium ranelate for five years.

## **Intervention Type**

Drug

## **Phase**

Phase III

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

Strontium ranelate

## **Primary outcome(s)**

The following will be assessed annually during the treatment:

1. Dual X-ray absorptiometry (DXA)
2. Vertebral fractures radiographs in patients having had vertebral radiographs in SOTI or TROPOS
3. Occurrence of peripheral fractures

## **Key secondary outcome(s)**

Safety

## **Completion date**

31/12/2009

## **Eligibility**

### **Key inclusion criteria**

1. Caucasian women
2. Postmenopausal
3. Osteoporosis
4. Having participated up to the SOTI or TROPOS M060 visit or withdrawn under study treatment from the SOTI or TROPOS study within a 6-month period preceding the theoretical M060 visit

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

Female

### **Key exclusion criteria**

1. Patients having attended the M060 or withdrawn SOTI-TROPOS visit at a time greater than one year prior to the inclusion visit of the CL3-12911-012 protocol
2. Significant concomitant disease (evolutive major illnesses)
3. Severe disease interfering with bone metabolism

**Date of first enrolment**

09/09/2002

**Date of final enrolment**

31/12/2009

## Locations

**Countries of recruitment**

United Kingdom

Australia

Belgium

Denmark

France

Germany

Hungary

Italy

Poland

Spain

Switzerland

**Study participating centre**

Unité d'Exploration du Métabolisme Osseux

Liege

Belgium

4020

## 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="#">Results article</a>	results	01/03/2012		Yes	No
<a href="#">Basic results</a>				No	No