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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.

Submission date 05/09/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 16/05/2008	**Overall study status** Completed	
Last Edited 18/04/2018	**Condition category** Musculoskeletal Diseases	

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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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 TReatment 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

Secondary study design
Non randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Not Specified

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

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 measure
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

Secondary outcome measures
Safety

Overall study start date
09/09/2002

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

Age group
Adult

Sex
Female

Target number of participants
3,000

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
Australia

Belgium

Denmark

France

Germany

Hungary

Italy

Poland

Spain

Switzerland

United Kingdom

Study participating centre
Unité d'Exploration du Métabolisme Osseux
Liege
Belgium
4020

Sponsor information

Organisation
Institut de Recherches Internationales Servier (France)

Sponsor details
50 rue Carnot
Suresnes
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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

Current version as of 28/03/2018:
Summary results are published in https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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.

Previous version as of 24/01/2018:
Publication plan:
All phases - Interventional studies ending before 01/10/2018: Summary results will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
All phases - Interventional studies ending after 01/10/2018: Summary results and a lay summary will be published on https://clinicaltrials.servier.com/ within 12 months after the end of the study.
Phase 3 only - The results will be published in scientific literature within 18 months after the end of the study.

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 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
Results article	results	01/03/2012		Yes	No