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

Submission date 20/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 15/06/2010	**Overall study status** Completed	
Last Edited 20/04/2020	**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
2009-014270-18

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Non randomised controlled trial

Study setting(s)
Hospital

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

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

Overall study start date
27/01/2010

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

Age group
Adult

Sex
Both

Target number of participants
60

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)

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
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
Basic results			20/04/2020	No	No