ISRCTN59279012 https://doi.org/10.1186/ISRCTN59279012

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

Submission date 03/05/2010	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 28/05/2010	**Overall study status** Completed	
Last Edited 18/04/2018	**Condition category** Nutritional, Metabolic, Endocrine	

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
2009-013935-39

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

CL3-06911-002

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 insufficiency in the treatment of osteoporotic postmenopausal women and men. A prospective, international phase III study with a 6-month double-blind period to assess the efficacy and safety of a daily oral administration of S06911 versus S12911 (strontium ranelate 2g) and a 6-month open-labelled extension for a subgroup of patients to assess safety of a daily oral administration of S06911.

Study objectives
To demonstrate the efficacy of S06911 on the correction of vitamin D insufficiency.

Please note that as of 19/11/2012, Denmark was removed from the countries of recruitment.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Randomised double-blind 2 parallel group trial followed by an open-labelled one treatment study

Primary study design
Interventional

Secondary study design
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 insufficiency

Interventions
First period: one sachet per day of strontium ranelate/vitamin D3 fixed combination versus strontium ranelate alone
Second period: strontium ranelate/vitamin D3 fixed combination

The total duration of treatment and the total duration of follow-up for our interventions is 6 or 12 months.

Intervention Type
Supplement

Phase
Phase III

Drug/device/biological/vaccine name(s)
Strontium ranelate, Vitamin D3

Primary outcome measure
Evaluate the serum 25-OH vitamin D3 levels over 3 months of treatment

Secondary outcome measures
1. Evaluate the serum 25-OH vitamin D3 levels after 6 months
2. Bone mineral density (BMD) from baseline to 12 months
3. Evaluate the safety at M1 and each 3 months

Overall study start date
27/01/2010

Completion date
22/07/2011

Eligibility

Key inclusion criteria
1. Osteoporotic men and osteoporotic post-menopausal women
2. Age superior or equal 50 years, either sex
3. Caucasian
4. 25-OH vitamin D3 serum concentration greater than 22.5 nmol/L

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
500

Key exclusion criteria
1. Progressive major illness, uncontrolled active disease, skeletal disease
2. History or increased risk of deep venous thrombosis or pulmonary embolism
3. History of intolerance, allergy or severe hypersensitivity with study drugs

Date of first enrolment
27/01/2010

Date of final enrolment
22/07/2011

Locations

Countries of recruitment
Austria

Belgium

Czech Republic

Finland

France

Germany

Hungary

Poland

Russian Federation

Slovakia

Spain

Switzerland

United Kingdom

Study participating centre
Hôpital Cantonal
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
Results article	results	04/02/2014		Yes	No