

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
Registration date 28/05/2010	Overall study status Completed	☐ Protocol
Last Edited 18/04/2018	Condition category Nutritional, Metabolic, Endocrine	☐ Statistical analysis plan
		☒ Results
		☐ 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

Clinical Trials Information System (CTIS)

2009-013935-39

Protocol serial number

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

Primary study design

Interventional

Study design

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

United Kingdom

Austria

Belgium

Czech Republic

Finland

France

Germany

Hungary

Poland

Russian Federation

Slovakia

Spain

Switzerland

Study participating centre

Hôpital Cantonal

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?
Results article	results	04/02/2014		Yes	No
Basic results				No	No