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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

Registration date
15/06/2010

Last Edited
20/04/2020

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
2009-014270-18

Protocol serial number
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

Primary study design
Interventional

Study design
Prospective open-labelled phase III study

Study type(s)
Treatment

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

Key secondary outcome(s)
1. Evaluate the efficacy over 12 months of treatment on the correction of vitamin D deficiency
2. Safety evaluation each 3 months

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

Healthy volunteers allowed
No

Age group
Adult

Sex
All

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)

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?
Basic results				No	No
Basic results			20/04/2020	No	No