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

Submission date
03/05/2010

Registration date
28/05/2010

Last Edited
18/04/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Nutritional, Metabolic, Endocrine

[_] 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

Contact name
Prof Rene Rizzoli

Contact details
Hôpital Cantonal
Département de réhabilitation et gériatrie
Genève 14
Switzerland
1211

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

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

Primary study design
Interventional

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