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Efficacy of strontium ranelate versus placebo on the time to fracture healing in osteoporotic men and osteoporotic post-menopausal women

Submission date
28/05/2010

Registration date
05/07/2010

Last Edited
21/04/2020

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)
2009-014271-41

Protocol serial number
CL3-12911-035

Study information

Scientific Title
A multicentre, prospective, randomised, double-blind, placebo-controlled, international study to assess the effects of 2 g per day of strontium ranelate versus placebo on the time to fracture healing in osteoporotic men and women

Acronym
The Fracture healing study

Study objectives
To demonstrate the efficacy of strontium ranelate 2 g versus placebo in accelerating radiological healing of distal radius fractures.

Please note that as of 27/11/2012, Belgium, Russian Federation and Ukraine were added to 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 placebo-controlled study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Radius fracture, Osteoporosis

Interventions
One daily administration of strontium ranelate 2 g or placebo during 24 weeks. There is no visit after the last intake at week-24.

Intervention Type
Other

Phase
Phase III

Primary outcome(s)
Time to radiological healing. Radiological evaluation will be performed at baseline, at week 4, 6, 7, 8, 9, 10, 12, 14 and at the last study visit. No radiography will be performed once radiological healing is complete, except at the last study visit.

Key secondary outcome(s))

1. Other radiological evaluations, performed at baseline, at week 4, 6, 7, 8, 9, 10, 12, 14 and at the last study visit. No radiography will be performed once radiological healing is complete, except at the last study visit.
2. Clinical evaluation (including mobility, quality of life, etc), performed at least once every 4 weeks from baseline to week 18 and at the last study visit
3. Safety evaluation, performed at least once every 4 weeks from baseline to week 18 and at the last study visit

Completion date
31/03/2012

Eligibility

Key inclusion criteria
1. Osteoporotic men and osteoporotic post-menopausal women
2. Aged superior or equal to 50 years
3. Patient with a fracture of the distal radius (Colles' fracture)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Senior

Sex
All

Total final enrolment
217

Key exclusion criteria
1. Fractures not meeting inclusion criteria (including displaced radius fractures)
2. Concomitant treatments likely to interfere with bone metabolism

Date of first enrolment
01/05/2010

Date of final enrolment
31/03/2012

Locations

Countries of recruitment
United Kingdom

Belgium

Brazil

Czech Republic

France

Germany

Hungary

Italy

Russian Federation

Ukraine

Study participating centre
University of Florence
Florence
Italy
50139

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 1st January 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			21/04/2020	No	No