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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	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 05/07/2010	**Overall study status** Completed	
Last Edited 21/04/2020	**Condition category** Musculoskeletal Diseases	

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 Maria Brandi

Contact details
University of Florence
Department of Internal Medicine
Division of Rheumatology and Metabolic bone Disease
Viale Pieraccini, 18
Florence
Italy
50139

Additional identifiers

EudraCT/CTIS number
2009-014271-41

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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
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 measure
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.

Secondary outcome measures
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

Overall study start date
01/05/2010

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

Age group
Senior

Sex
Both

Target number of participants
200

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
Belgium

Brazil

Czech Republic

France

Germany

Hungary

Italy

Russian Federation

Ukraine

United Kingdom

Study participating centre
University of Florence
Florence
Italy
50139

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
Publication plan:
Summary results are published on https://clinicaltrials.servier.com.
For interventional Phase III studies ending after the 1st January 2014, the results are/will be published in scientific literature.

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 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