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

Submission date	Recruitment status	Prospectively registered
28/05/2010	No longer recruiting	☐ Protocol
Registration date	Overall study status	Statistical analysis plan
05/07/2010	Completed	[X] Results
Last Edited	Condition category	Individual participant data
21/04/2020	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

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Contact details

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Additional identifiers

EudraCT/CTIS number 2009-014271-41

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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