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Efficacy of strontium ranelate in the management of long bone fractures in osteoporotic patients

Submission date	Recruitment status	[ ] Prospectively registered
21/06/2010	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
09/07/2010	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

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Additional identifiers

EudraCT/CTIS number
2009-017039-16

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CL3-12911-036

Study information

Scientific Title
Effect of strontium ranelate (2 g per day) in the management of long bone fractures with delayed-union or non union: an international open label study in patients with osteoporosis

Study objectives
Current study hypothesis as of 30/11/2012:
To assess the effects of strontium ranelate 2 g/day in the management of aseptic fractures of long bones with delayed union or non-union

As of 27/07/11:
To assess the effects of strontium ranelate 2 g/day in the management of aseptic fractures of limbs with delayed union or non-union

As of 09/07/10:
To assess the effects of strontium ranelate 2 g/day in the management of aseptic fractures of the lower limbs with delayed union or non-union.

Please note that as of 30/11/2012, the following changes were made to the record:
1. The anticipated end date was updated from 31/12/2011 to 30/04/2013
2. France and Germany were removed from the countries of recruitment, and Romania was added
3. The public title was previously "Efficacy of strontium ranelate in the management of limb fractures in osteoporotic patients"
4. The scientific title was previously "Effect of strontium ranelate (2 g per day) in the management of limb fractures with delayed-union or non union: an international open label study in patients with osteoporosis"

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval was obtained before recruitment of the first participants

Study design
Open labelled treatment period of 12 months

Primary study design
Interventional

Secondary study design
Non 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
Lower long bone fracture

Interventions
One sachet of strontium ranelate (2 g per day) during 12 months.

Intervention Type
Other

Phase
Phase III

Primary outcome measure
1. Radiological union of the fracture, performed every 2 or 3 months during the study
2. Clinical assessments (including pain, quality of life, mobility, etc.), performed every 2 or 3 months during the study (mobility test performed every 6 months)
3. Safety evaluations, performed every 2 or 3 months during the study

Secondary outcome measures
No secondary outcome measures

Overall study start date
15/06/2010

Completion date
30/04/2013

Eligibility

Key inclusion criteria
30/11/2012: Current inclusion criteria as of 01/09/2011:
1. Men aged > 18 years and postmenopausal women menopause >2 years
2. Patient with long bone fracture with a delayed union or a non-union

As of 27/07/11:
1. Osteoporotic men and osteoporotic postmenopausal women.
2. Patient with a fracture of limb with a delayed union or a non-union

As of 09/07/10:
1. Osteoporotic men and osteoporotic postmenopausal women
2. Patient with a fracture of the lower limbs with a delayed union or a non-union

Participant type(s)
Patient

Age group

Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Total final enrolment
48

Key exclusion criteria
1. Fractures not meeting inclusion criteria (including pathological fractures)
2. Bone-related disease other than osteoporosis
3. Concomittant treatments interfering with bone metabolism

Date of first enrolment
15/06/2010

Date of final enrolment
30/04/2013

Locations

Countries of recruitment
Brazil

Czech Republic

France

Hungary

Italy

Portugal

Romania

Study participating centre
Hôpital Saint Antoine
Paris Cedex 12
France
F 75571

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
Abstract results	abstract from ACR/ARHP Annual Meeting	05/10/2013		No	No
Basic results			21/04/2020	No	No