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Long-term effects of strontium ranelate on knee osteoarthritis symptoms: a two year prospective, randomised, placebo-controlled study

Submission date
29/09/2006

Registration date
12/10/2006

Last Edited
28/03/2018

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Musculoskeletal Diseases

[X] 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
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Additional identifiers

Protocol serial number
CL3-12911-028

Study information

Scientific Title
Long-term effects of strontium ranelate on knee osteoarthritis symptoms. A 2-year prospective, randomised, placebo-controlled study.

Study objectives
To assess the effectiveness on algofunctional symptoms of knee osteoarthritis.

Please note that as of 27/11/2012, the anticipated end date was updated from 30/06/2009 to 30 /12/2009

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee approval obtained on 07/09/2006 (n° 154): Comité dEthique Hospitalo-Facultaire Universitaire de Liège.

Primary study design
Interventional

Study design
Randomised, double-blind, parallel-group, placebo-controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Osteoarthritis

Interventions
Strontium ranelate versus placebo.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Strontium ranelate

Primary outcome(s)
Changes in the algofunctional behaviour of the target knee.

Key secondary outcome(s)
1. Algofunctional assessment
2. Radiographic assessment of knee osteoarthritis
3. Physical examination

Completion date
30/12/2009

Eligibility

Key inclusion criteria
1. Caucasian males or females
2. Aged 45 years or over
3. Primary knee osteoarthritis
4. Under an effective contraceptive method for non-menopausal women

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Knee prosthesis already implanted, or foreseen to be implanted
2. Hip prosthesis already implanted or not well-tolerated or foreseen to be implanted
3. Previous osteotomy on the inferior limbs

Date of first enrolment
30/11/2006

Date of final enrolment
30/12/2009

Locations

Countries of recruitment
Belgium

Study participating centre
Policlinique Brull, 45 Quai Godefroid Kurth
Liège
Belgium
4020

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