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Protelos® evAluation iN THe osteoporotic mEn and wOmen under daily practice conditioNs

Submission date
10/10/2012

Recruitment status
No longer recruiting

Registration date
27/11/2012

Overall study status
Completed

Last Edited
22/01/2019

Condition category
Musculoskeletal Diseases

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims:
Osteoporosis affects postmenopausal women and elderly men, and causes loss of bone mass and damage to the bone structure. This leads to an increased risk of fractures. Death after such fractures is more likely. Protelos® is a medicine, which was shown to reduce fracture rates in postmenopausal women. Currently it has been approved for treatment of osteoporosis in men. In study we aim to observe the treatment of osteoporosis with Protelos® in men and postmenopausal women, and see if this has an effect in regards to pain reduction and quality of life.

Who can participate?
Men and postmenopausal women with osteoporosis who have an increased risk of fractures.

What does the study involve?
All patients involved in the study will be treated with Protelos®. The participants will be asked to attend a follow up visit after 3 months. During this visit, a routine investigation will be carried out where information on osteoporosis, other diseases the participant may have and other medications they are taking and pain will be completed. The participants will also be asked to fill out a quality of life questionnaire at each visit.

What are the possible benefits and risks of participating?
The patients have no particular benefits or risks of participating in this study. The treatment given to the participants is part of their daily routine and free to withdraw from the study at any time without giving a particular reason.

Where is the study run from?
The study will be carried out by orthopedic surgeons across Germany.

When is the study starting and how long is it expected to run for?
The study started in October 2012 and is due to end in May 2013. Participants will be recruited until February 2013.

Who is funding the study?
Servier Deutschland, GmbH.

Who is the main contact?
Dr Peter Martinka
peter.martinka@de.netgrs.com

Contact information

Type(s)
Scientific

Contact name
Prof Johann Diederich Ringe

Contact details
Westdeutsches Osteoporose-Zentrum
Klinikum Leverkusen gGmbH
Dhünnberg 60
Leverkusen
Germany
51375
-
ringe@klinikum-lev.de

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
IC4-12911-102-DEU

Study information

Scientific Title
Protelos® evaluation in the osteoporotic men and women under daily practice conditions. A multicentric prospective observational study

Acronym
PANTHEON

Study objectives
Effects of therapy with Protelos® (Strontium ranelate) on the pain perception and quality of life in men and postmenopausal women with osteoporosis under daily routine in an observational prospective multicentre trial carried out by orthopedic surgeons and general practitioners.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Freiburg Ethics Commission International (FEKI), 10/09/2012

Study design
Observational prospective multicentre open-label study

Primary study design
Observational

Secondary study design
Non-randomised controlled trial

Study setting(s)
Other

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
Osteoporosis

Interventions
Observational study to get information about therapy of osteoporosis with Protelos®; under daily routine practice by orthopedic surgeons and general practitioners.

The treatment decision must be made prior to study initiation. Treating physicians will confirm the diagnosis of osteoporosis at baseline. After the baseline visit, there is a final visit after approx. 3 months.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
1. Effects of Protelos® on the osteoporosis-related pain
2. Effects of Protelos® on quality of life assessed by EQ-5D
3. Effects of Protelos® on analgesics prescription
4. Information about how Protelos® SmPC and patient information are followed via

standardised documentation
5. Analysis of general tolerability of Protelos® under routine conditions via standardised adverse reactions documentation and standardised documentation of therapy discontinuation
6. Analysis of unknown adverse drug reactions via standardised documentation

Secondary outcome measures
No secondary outcome measures

Overall study start date
08/09/2012

Completion date
31/05/2013

Eligibility

Key inclusion criteria
1. Adult men with osteoporosis at increased risk of fractures
2. Postmenopausal women with osteoporosis at increased risk of fractures

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
2960

Key exclusion criteria
1. Does not meet inclusion criteria
2. In addition, doctors involved in the trial should follow the Summary of Product Characteristics (SmPC) for Protelos®, which includes the following contraindications:
2.1 Hypersensitivity to the active substance or to any of the excipients.
2.2 Current or previous venous thromboembolic events (VTE), including deep vein thrombosis and pulmonary embolism.
2.3 Temporary or permanent immobilisation due to e.g. post-surgical recovery or prolonged bed rest.

Date of first enrolment
08/09/2012

Date of final enrolment
01/02/2013

Locations

Countries of recruitment
Germany

Study participating centre
Westdeutsches Osteoporose-Zentrum
Leverkusen
Germany
51375

Sponsor information

Organisation
Servier Deutschland GmbH (Germany)

Sponsor details
c/o Dr. Peter Martinka
Medical Affairs Officer
Elsenheimerstraße 53
München
Germany
80687
+49 (0)89 5709501
peter.martinka@de.netgrs.com

Sponsor type
Industry

Website
http://www.servier.de

ROR
https://ror.org/05wk4ae67

Funder(s)

Funder type
Industry

Funder Name
Servier Deutschland GmbH (Germany)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Abstract results	results presented at DGRh	17/09/2014		No	No