

Protelos® evAluation iN The osteoporotic mEn and wOmen under daily practice conditionS

Submission date 10/10/2012	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 27/11/2012	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 22/01/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

No secondary outcome measures

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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)

ROR

https://ror.org/05wk4ae67

Funder(s)

Funder type

Industry

Funder Name

Servier Deutschland GmbH (Germany)

Results and Publications

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