PERSPECTIVES: Protelos® for postmenauposal osteoporotic patients with previous therapies

Submission date	Recruitment status No longer recruiting	Prospectively registered		
20/02/2009		☐ Protocol		
Registration date 15/05/2009	Overall study status Completed	Statistical analysis plan		
		[X] Results		
Last Edited	Condition category	Individual participant data		
23/01/2019	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

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

IC4-12911-101-DEU

Study information

Scientific Title

PERSPECTIVES: Protelos® for postmenauposal osteoporotic patients with previous therapies - an observational prospective multi-centre study

Acronym

PERSPECTIVES

Study objectives

Effects of Protelos® therapy on osteoporosis and osteoporosis symptoms under practice daily routine in a non-interventional trial.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics Committee of Charité - University Medicine Berlin (Charité - Universitätsmedizin Berlin), Campus Benjamin Franklin, approved on 08/01/2009 (ref: EA4/101/08)

Study design

Observational prospective longitudinal multi-centre study

Primary study design

Observational

Secondary study design

Multi-centre

Study setting(s)

Not specified

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

Postmenopausal osteoporosis

Interventions

- 1. To get information on the evolution of osteoporosis therapy in the treatment postmenopausal osteoporosis via standardised documentation
- 2. To get information on comobidity and comedication in postmenopausal osteoporosis via standardised documentation.
- 3. Evaluation of osteoporose-associated pain via Visual Analogue Scale (VAS)
- 4. Recording of new osteoporose-associated fractures via standardised documentation
- 5. Evaluation of the efficacy under routine conditions and tolerability of Protelos via Ordinal

Scale

- 6. Recording of the osteoporosis-comedications via standardised documentation
- 7. Analysis of the adverse drug reactions of Protelos via standardised adverse drug reactions documentation
- 8. A patients questionnaire (at initiation visit and at final visit) will provide information on:
- 8.1. Evaluation of the quality of life (patients questionnaire including 9 questions = ordinal scale)
- 8.2. Evaluation of the compliance, persistence and adherence with Protelos®
- 8.3. Evaluation of non-medical therapies of postmenopausal osteoporosis (standardised patients questionnaire)

Total duration of follow-up: 3 months

Intervention Type

Drug

Phase

Phase IV

Drug/device/biological/vaccine name(s)

Strontium ranelate (Protelos®)

Primary outcome measure

- 1. Efficacy under routine conditions: ordinal scale (very good, good, moderate, bad)
- 2. Tolerability: ordinal scale (very good, good, moderate, bad)
- 3. Pain (VAS; 0 = no pain 10 = unbearable pain)
- 4. Fractures (standardized documentation)
- 5. Quality of life (patients questionnaire including 9 questions = ordinal scale)
- 6. Compliance, persistence, adherence (standardised patients questionnaire)

All data will be assessed at initiation visit and 3 months later at final visit.

Secondary outcome measures

No secondary outcome measures

Overall study start date

02/02/2009

Completion date

30/09/2009

Eligibility

Key inclusion criteria

Postmenopausal osteoporotic women, treated with strontium ranelat (Protelos®).

Participant type(s)

Patient

Age group

Adult

Sex

Female

Target number of participants

2,250 patients/ max. 750 doctors

Key exclusion criteria

Does not meet inclusion criteria

Date of first enrolment

02/02/2009

Date of final enrolment

30/09/2009

Locations

Countries of recruitment

Germany

Study participating centre Servier Deutschland GmbH

Munich Germany 80687

Sponsor information

Organisation

Servier Deutschland GmbH (Germany)

Sponsor details

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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?
Results article	results	01/01/2012		Yes	No