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PERSPECTIVES: Protelos® for postmenauposal osteoporotic patients with previous therapies

Submission date	Recruitment status	[_] Prospectively registered
20/02/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/05/2009	Completed	[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

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Additional identifiers

Protocol serial number
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)

Primary study design
Observational

Study design
Observational prospective longitudinal multi-centre study

Study type(s)
Treatment

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(s)
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.

Key secondary outcome(s)
No secondary outcome measures

Completion date
30/09/2009

Eligibility

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

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

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)

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?
Results article	results	01/01/2012		Yes	No