

PERSPECTIVES: Protelos® for postmenopausal osteoporotic patients with previous therapies

Submission date 20/02/2009	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/05/2009	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
Last Edited 23/01/2019	Condition category Musculoskeletal Diseases	<input type="checkbox"/> 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

Dr Martin Kühn

Contact details

Servier Deutschland GmbH
Elsenheimer Str. 53
Munich
Germany
80687
+49 89 57095308
martin.kuehn@de.netgrs.com

Additional identifiers

Protocol serial number

IC4-12911-101-DEU

Study information

Scientific Title

PERSPECTIVES: Protelos® for postmenopausal 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

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 comorbidity 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