European Program of Post-Authorization Safety Studies for Protelos®/Osseor® through EU-ADR Alliance

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Study | Finalised

Administrative details

Contact details

Study institution contact
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Study contact

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Primary lead investigator
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Primary lead investigator

PURI
https://redirect.ema.europa.eu/resource/23302

EU PAS number
EUPAS9117

Study ID
23302

DARWIN EU® study
No

Study countries
Denmark
Italy
Netherlands
Spain
United Kingdom

Study description
PASS with a multi-national multi-database approach (population-based cohort study and nested case control analysis in a cohort of new users of strontium ranelate (SR) or oral bisphosphonates) and with the following objectives:1. To study the effectiveness of the newly established risk minimization measures by characterizing utilization patterns of SR and estimating the prevalence of contraindications (CI) and restrictions of indication amongst incident and prevalent SR users. 2. To estimate and compare the incidence rates of cardiac and thromboembolic events in new users of SR and new users of bisphosphonates.

Study status
Finalised

Research institution and networks

Institutions

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain
First published: 05/10/2012
Last updated 23/02/2024

Institution | Educational Institution | Laboratory/Research/Testing facility | Not-for-profit | ENCePP partner

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark
First published: 20/07/2021

Last updated
02/04/2024

Institution

Educational Institution

ENCePP partner

Department of Medical Informatics - Health Data Science, Erasmus Medical Center (ErasmusMC)

Netherlands
First published: 03/11/2022
Last updated
02/05/2024

Institution

Educational Institution

ENCePP partner

Fundació Institut Universitari per a la Recerca a l'Atenció Primària de Salut Jordi Gol i Gurina, IDIAPJGol

Spain
First published: 05/10/2012
Last updated
23/02/2024

Institution

Educational Institution

Laboratory/Research/Testing facility

Not-for-profit

ENCePP partner

Società Italiana di Medicina Generale e delle Cure Primarie (SIMG)

First published: 01/02/2024
Last updated
01/02/2024

Institution

Patient organisation/association

Networks

EU-ADR Alliance

First published: 01/02/2024
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Network

Study timelines

Date when funding contract was signed
Planned:
01/04/2015
Actual:
01/04/2015

Data collection
Planned:
01/04/2015
Actual:
01/06/2015

Start date of data analysis
Actual:
15/07/2015

Date of interim report, if expected
Actual:
24/11/2015

Date of final study report
Planned:
30/11/2017
Actual:
23/11/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Les Laboratoires Servier

Study protocol

2015_01_07_EU ADR Alliance SR protocol_final_clean_redacted.pdf(1.61 MB)

2017_04_28_EU ADR Alliance SR protocol_final_Updated_April_2017_clean_redacted.pdf (2.18 MB)

Regulatory

Was the study required by a regulatory body?
Yes

Is the study required by a Risk Management Plan (RMP)?
EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:
Disease /health condition
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Assessment of risk minimisation measure implementation or effectiveness
Drug utilisation
Safety study (incl. comparative)

Data collection methods:
Secondary data collection

Main study objective:

Effectiveness of RMM:Characterize utilization patterns of SREstimate the prevalence of CI in SR users Calculate the prevalence of SR users who fulfill the new indicationsSafety:Estimate incidence rates of cardiac and thromboembolic events in SR users with and without CICompare the risk of cardiac an

Study Design

Non-interventional study design
Case-control
Cohort

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name
STRONTIUM RANELATE

Anatomical Therapeutic Chemical (ATC) code
100000097127
strontium ranelate

Medical condition to be studied
Osteoporosis

Population studied

Short description of the study population
All osteoporosis patients that are registered for at least one year with one of the participating databases during the study period who are strontium ranelate users and new oral bisphosphonates users (BP).

Age groups
Adults (46 to < 65 years)
Adults (65 to < 75 years)
Adults (75 to < 85 years)
Adults (85 years and over)

Special population of interest
Other

Special population of interest, other
Osteoporosis patients

Estimated number of subjects
100000

Study design details

Outcomes
Contraindications, new indication/prescribing conditions and safety endpoints

Data analysis plan
Effectiveness of RMM:-Incidence/prevalence of SR use, characteristics of users and patterns of use, with stratification by period (before/after implementation of RMM), age and sex.-Prevalence of CI and new indication/restrictions of use, by period, age and sex. Interrupted time series analyses will be used to assess the impact of RMM on these criteria.Safety:-Crude, as well as age and sex-specific incidence rates of the safety endpoints will be estimated separately in new users of SR and bisphosphonates (BP), stratified by period and history of CI.-Conditional logistic regression will be used in nested case-control analyses to compare the risk of the safety endpoints between current use of SR and past use and current use of BP, in persons without CI. Analyses will be stratified by period.All estimates will be calculated by databases and pooled according to a meta-analysis approach. A mega-pooled analysis will estimate the effects putting all individual data together.

Documents

Results tables
Abstracts - Final Reports.pdf(76.41 KB)

Data management

Data sources

Data source(s)
THIN® (The Health Improvement Network®)
Danish registries (access/analysis)
Health Search/IQVIA Health Longitudinal Patient Database
IPCI

Data sources (types)
Administrative data (e.g. claims)
Drug dispensing/prescription data
Electronic healthcare records (EHR)
Other

Data sources (types), other
Hospital admission data

Use of a Common Data Model (CDM)

CDM mapping
No

Data quality specifications

Check conformance
Unknown

Check completeness
Unknown

Check stability
Unknown

Check logical consistency
Unknown

Data characterisation

Data characterisation conducted
Unknown