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

First published: 27/03/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

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 institutions 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: 23/05/2025

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

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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

Last updated: 01/02/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Prieto-Alhambra

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2015

Actual: 01/04/2015

Study start date

Planned: 01/04/2015

Actual: 01/06/2015

Data analysis start date

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 use of data

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 and thromboembolic events between new users of SR and of oral bisphosphonates without CI

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

(M05BX03) strontium ranelate

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

Study results

Abstracts - Final Reports.pdf (76.41 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Danish registries (access/analysis)

Health Search/IQVIA Health Longitudinal Patient Database

Integrated Primary Care Information (IPCI)

The Information System for Research in Primary Care (SIDIAP)

Data sources (types)

Administrative healthcare records (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