

# 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

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### Study ID

23302


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### DARWIN EU® study

No

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### Study countries

 Denmark

 Italy

 Netherlands

 Spain

## 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.

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## 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

**Last updated:** 23/05/2025

**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

[christine.bouillant@fr.netgrs.com](mailto:christine.bouillant@fr.netgrs.com)

### **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

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### **Study start date**

Planned: 01/04/2015

Actual: 01/06/2015

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### **Data analysis start date**

Actual: 15/07/2015

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### **Date of interim report, if expected**

Actual: 24/11/2015

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### **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

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### **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

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**Study type:**

Non-interventional study

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**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

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**Main study objective:**

Effectiveness of RMM: Characterize utilization patterns of SR  
Estimate the prevalence of CI in SR users  
Calculate the prevalence of SR users who fulfill the new indications  
Safety: Estimate incidence rates of cardiac and thromboembolic events in SR users with and without CI  
Compare 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

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**Anatomical Therapeutic Chemical (ATC) code**

(M05BX03) strontium ranelate

strontium ranelate

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**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).

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**Age groups**

- Adults (46 to < 65 years)
  - Adults (65 to < 75 years)
  - Adults (75 to < 85 years)
  - Adults (85 years and over)
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**Special population of interest**

Other

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**Special population of interest, other**

Osteoporosis patients

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## **Estimated number of subjects**

100000

# Study design details

## **Outcomes**

Contraindications, new indication/prescribing conditions and safety endpoints

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## **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)

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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)

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### **Data sources (types)**

[Administrative healthcare records \(e.g., claims\)](#)

[Drug dispensing/prescription data](#)

[Electronic healthcare records \(EHR\)](#)

[Other](#)

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### **Data sources (types), other**

Hospital admission data

## Use of a Common Data Model (CDM)

### **CDM mapping**

No

## Data quality specifications

**Check conformance**

Unknown

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

**Data characterisation conducted**

Unknown