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

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### Administrative details

### Contact details

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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

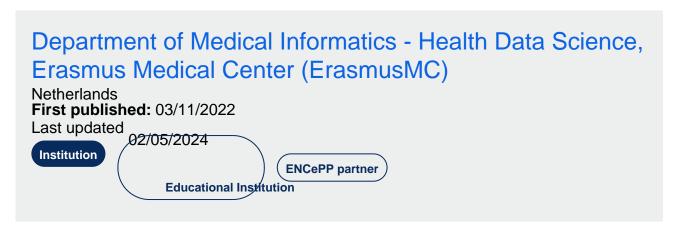


## Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

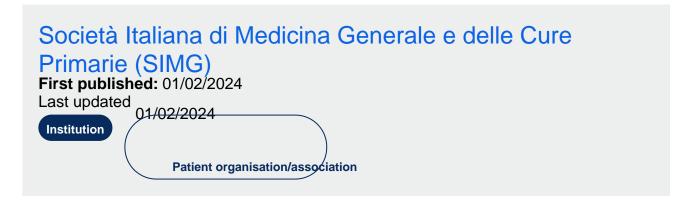
Denmark

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### **Networks**

### **EU-ADR Alliance**

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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

### 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 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

#### The Information System for Research in Primary Care

### **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