Database study of lenalidomide (Revlimid®) in Germany: Monitoring off-label use

First published: 08/07/2014

Last updated: 02/07/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS7023

Study ID

20223

DARWIN EU® study

No

Study countries

☐ Germany

Study description

In 2007 and 2008, lenalidomide, a derivate of thalidomide, was in combination with dexamethasone indicated for the treatment of multiple myeloma in patients who have received at least one prior therapy. In this study, based on claims data with around 14 million enrollees, off-label use of lenalidomide in Germany was considered. The study is part of a risk management plan required by EMA (European Medicines Agency) and the German Federal Institute for Drugs and Medical Devices (BfArM) due to the teratogenic potential of the drug.

Study status

Finalised

Research institutions and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany

First published: 29/03/2010

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Institution | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Oliver Riedel

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/04/2008

Actual: 15/04/2008

Study start date

Planned: 06/05/2008

Actual: 06/05/2008

Data analysis start date

Planned: 08/05/2009

Actual: 08/05/2009

Date of interim report, if expected

Planned: 05/05/2014

Actual: 05/05/2014

Date of final study report

Planned: 31/12/2014

Actual: 17/12/2014

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Celgene GmbH

Regulatory

Was the study required by a regulatory body?

Yes

Is the study required by a Risk Management Plan (RMP)?

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The objectives are to determine frequency and proportion of off-label use of lenalidomide by indication in 2008 and to investigate probable off label indications for lenalidomide. The initial dose of lenalidomide, dose changes and the number of lenalidomide dispensations per patient for on-label and off-label users were characterised. Incidence rates of lenalidomide use in 2008 were calculated.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

REVLIMID

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

LENALIDOMIDE

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

Adult patients with multiple myeloma with off-label use of lenalidomide in Germany.

Age groups

- Adults (18 to < 46 years)
- 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

Multiple myeloma patients

Estimated number of subjects

500

Study design details

Outcomes

frequency of off-label use

Data analysis plan

Descriptive analyses were conducted for all users of lenalidomide with respect to demographic characteristics, i.e. sex, age and federal state of residence, death and frequency of dispensations. Incidence rates of lenalidomide use by

sex, age and federal state of residence were determined. Prevalence and incidence rates of lenalidomid use were calculated with 95% confidence intervals. Demographics and comorbidities are determined for patient with off-label use.

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)

German Pharmacoepidemiological Research Database

Data sources (types)

Administrative healthcare records (e.g., claims)

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