Database Study of Thalidomide (Thalidomide Celgene®) in Germany: Monitoring Off-Label Use

First published: 08/07/2014

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/16822

EU PAS number

EUPAS7020

Study ID

16822

DARWIN EU® study

No

Study countries

☐ Germany

Study description

The immunomodulator thalidomide, in combination with melphalan and prednisone is indicated for the first-line treatment of multiple myeloma in patients 65 years of age and patients for which a high-dose chemotherapy is not suitable. Aim of this project is to analyse the extent of the ambulatory off-label use (use of a drug outside the terms of its marketing authorisation) of thalidomide. 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

Last updated: 26/02/2024

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: 03/12/2010

Actual: 03/12/2010

Data analysis start date

Planned: 13/04/2011

Actual: 12/04/2011

Date of interim report, if expected

Planned: 10/06/2014

Actual: 10/06/2014

Date of final study report

Planned: 31/12/2014

Actual: 31/12/2014

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)?

Not applicable

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 of this study were to determine off-label use of thalidomide by indication in the years 2009 (subproject 1) and 2010 (subproject 2) and to investigate probable indications for thalidomide use in off-label users. On-label and off-label users of thalidomide were characterised. Furthermore, the incidence rates of thalidomide use were investigated.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine, other

Thalidomide Celgene

Medical condition to be studied

Plasma cell myeloma

Population studied

Short description of the study population

Myeloma patients with off-label use of thalidomide in 2009 and 2010.

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

Plasma cell myeloma patients

Estimated number of subjects

200

Study design details

Outcomes

frequency of off-label use

Data analysis plan

Descriptive analyses were conducted for all users of thalidomide with respect to demographic characteristics, i.e. sex, age and federal state of residence, death and frequency of dispensations. Incidence rates of thalidomide use by sex, age and federal state of residence were determined. Prevalence and incidence rates of thalidomide use were calculated with 95% confidence intervals. Demographics and comorbidities are determined for patient with off-label use.

Data management

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