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 institution and networks

Institutions

Leibniz Institute for Prevention Research and Epidemiology - BIPS

Germany
First published: 29/03/2010
Last updated
26/02/2024

Institution

ENCePP partner

Not-for-profit

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 data collection

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 data (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