Claims Database Study of Utilization Patterns of Dimethyl Fumarate in Germany

First published: 13/10/2017

Last updated: 01/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21305

Study ID

29058

DARWIN EU® study

No

Study countries

Germany

Study description

The primary objective of this study is to estimate the proportion of DMF use that is prescribed "on-label" versus "off-label". The secondary objectives are: To describe the demographic characteristics and medical history of DMF users, To

describe prescription drug history and concomitant medication use of DMF users, To describe the duration of therapy in participants newly initiating DMF treatment, To describe the medical specialties of DMF prescribers.

Study status

Finalised

Research institutions and networks

Institutions

Biogen

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Institution

Contact details

Study institution contact

Study Director Biogen ctrr@biogen.com

Study contact

ctrr@biogen.com

Primary lead investigator

Study Director Biogen

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 06/10/2014

Actual: 15/10/2014

Study start date
Actual: 01/09/2013

Data analysis start date
Actual: 31/12/2016

Date of final study report
Planned: 02/10/2017

Actual: 20/10/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

109MS409 Protocol FINAL v1.0 06OCT2014_Redacted.pdf (543.98 KB)

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)

Other study registration identification numbers and links

109MS409

NCT02969304https://clinicaltrials.gov/ct2/show/NCT02969304?term=NCT02969304&rank

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 primary objective of this study is to estimate the proportion of DMF use that is prescribed “on-label” versus “off-label”.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Retrospective analysis of a research database

Study drug and medical condition

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

DIMETHYL FUMARATE

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

All patients who were users of dimethyl fumarate (DMF) in the post launch study period were retrieved from the database.

Patients were included in the study if they satisfied the following eligibility criteria:
1. Treatment initiation with DMF on or after 1 March 2014 without a previous prescription for DMF in the 6 months prior to the index date

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Age groups

- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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 sclerosis patients

Estimated number of subjects

500

Study design details

Outcomes

Proportion of dimethyl fumarate use that is prescribed "on-label" versus "off-label" in Germany. Demographic characteristics of dimethyl fumarate (DMF) users, Prescription drug history of DMF users, duration of therapy in participants newly initiating DMF treatment, number of medical specialists prescribing DMF as identified according to specialty-specific billing codes at outpatient visits, medical history of DMF users, concomitant medication use of DMF users.

Data analysis plan

This study is strictly descriptive (i.e. no hypothesis testing is being conducted). Demographic characteristics, concomitant medication, medication history, time on DMF and specialty of prescribing physician will be analysed separately by “on-label” or “off-label” use. All statistical analyses will be reported in a descriptive manner.Continuous data will be described by their mean, standard deviation, median, minimum, and maximum. Categorical data will be described by absolute and relative frequencies. A detailed description of the statistical analysis will be provided in the statistical analysis plan.

Documents

Study results

109MS409_ EUPASResultsPacket_Redacted.pdf (259.01 KB)

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 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