

Adherence to disease modifying drugs of patients with multiple sclerosis (ADAPIMS)

First published: 27/03/2013

Last updated: 26/03/2024

Study

Finalised

Administrative details

PURI

<https://redirect.ema.europa.eu/resource/16992>

EU PAS number

EUPAS3330

Study ID

16992

DARWIN EU® study

No

Study countries

☐ Germany

Study description

Objective is to evaluate the adherence of patients to disease modifying drugs

Study status

Finalised

Research institutions and networks

Institutions

Deutsches Arzneiprüfungsinstitut e.V. (DAPI)

Contact details

Study institution contact

Johanna Werning

Study contact

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Primary lead investigator

Johanna Werning

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/07/2012

Actual: 03/09/2012

Study start date

Planned: 01/01/2013

Actual: 06/05/2013

Data analysis start date

Planned: 01/05/2013

Actual: 01/04/2013

Date of final study report

Planned: 01/02/2016

Actual: 27/07/2015

Sources of funding

- Other

More details on funding

DAPI, TU Dresden

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

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:

To quantify persistence and compliance with disease modifying drugs for multiple sclerosis from a representative pharmacy dispensing database in Germany.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L03AB07) interferon beta-1a

interferon beta-1a

(L03AB08) interferon beta-1b

interferon beta-1b
(L03AX13) glatiramer acetate
glatiramer acetate

Population studied

Short description of the study population

Patients using disease modifying drugs (DMD) for multiple sclerosis who had their first prescription of any DMD between January 01, 2002, and December 31, 2006.

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

80000

Study design details

Outcomes

persistence with disease modifying drugs for multiple sclerosis (estimated from a pharmacy dispensing database with method of allowable gaps between refills), compliance with disease modifying drugs for multiple sclerosis (estimated from a pharmacy dispensing database with method of medication possession ratio)

Data analysis plan

Persistence will be quantified as the proportion of patients not exceeding the allowable gap between refills during follow-up (730 days from index prescription) as well as median duration of persistence. Compliance will be quantified as the proportion of patients with medication possession ratio exceeding 0.8. Differences in persistence and compliance will be analysed for the different types of disease modifying drugs (3 interferon products and glatiramer acetate) as well as by index year in order to estimate trends in persistence and compliance during recent years.

Documents

Study results

[Hansen_adherence DMD MS-DAPI_PLoS One 2015.pdf](#) (718.21 KB)

Study publications

[Hansen K, Schüssel K, Kieble M, Werning J, Schulz M, Friis R, et al. \(2015\) Adh...](#)

Data management

Data sources

Data source(s), other

DAPI database

Data sources (types)

[Drug dispensing/prescription 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

No