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

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## Administrative details

EU PAS number
EUPAS3330
Study ID
Study ID
16992
DARWIN EU® study
No 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 info@dapi.de

Study contact

info@dapi.de

## **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 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:

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

## **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), 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