Effectiveness of Tecfidera® in multiple sclerosis: a French cohort within the nationwide claims and hospital database (EVIDEMS)

First published: 20/11/2017

Last updated: 01/02/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/49938

EU PAS number

EUPAS21563

Study ID

49938

DARWIN EU® study

No

Study countries

☐ France

Study description

Multiple sclerosis (MS) is an incapacitating, progressive, chronic neurological disorder that involves a selective, chronic inflammation and demyelination of the central nervous system. The severity of the disease varies from mildly forms to severe disabilities within a few years. Relapsing-remitting MS forms (RRMS) are the most common, and are characterized by the presence of relapses without disability progression between relapses. The aim of the disease modifying therapy is to reduce the frequency of relapses and to slow the disability progression. The first-line long-term treatments for RRMS were interferon beta-1a and 1b and glatiramer acetate, while Natalizumab and fingolimod have a Marketing Authorisation restricted to highly active RRMS. Two other oral drugs were approved recently for the treatment of adult patients with MS: teriflunomide marketed since November 2014 and Dimethyl fumarate prescribed within a hospital compassionate use program since March 2014, and officially reimbursed 25 June 2015 for prescription to outpatients. In the context of the renewal of the registration of Tecfidera® in 2020, this project was designed to assess the drug usage pattern in MS after Tecfidera® launch in France, and to compare the benefit of Tecfidera® to other drugs in current practice, and especially to the two other oral drugs, Aubagio® and Gilenya®, using the SNIIRAM nationwide claims and hospital database.

Study status

Finalised

Research institutions and networks

Institutions

Bordeaux PharmacoEpi, University of Bordeaux

France

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Institution | Educational Institution | Hospital/Clinic/Other health care facility | Not-for-profit | ENCePP partner

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Patrick Blin

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 20/11/2015

Study start date

Planned: 01/12/2017

Actual: 30/11/2017

Data analysis start date

Planned: 31/01/2018

Actual: 31/03/2018

Date of final study report

Planned: 31/03/2020

Actual: 20/04/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen France SAS

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

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

To assess the effectiveness of Tecfidera® on the frequency of relapses compared to the two other oral drugs (Aubagio® and Gilenya®), as well as injectable immunomodulatory drugs (IID) (Avonex®, Betaferon®, Copaxone®, Rebif®, Extavia®, Plegridy®).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AX07) dimethyl fumarate

dimethyl fumarate

Medical condition to be studied

Relapsing-remitting multiple sclerosis

Population studied

Short description of the study population

Adults patients with relapsing-remitting multiple sclerosis forms receiving Tecfidera® and other oral drugs including Aubagio® and Gilenya® identified from the SNIIRAM nationwide claims and hospital database.

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

Patients with relapsing-remitting multiple sclerosis

Estimated number of subjects

62000

Study design details

Outcomes

The primary outcome is the number of relapses occuring during the follow-up. The secondary outcome is the progression of disability defined as a reimbursed dispensation of equipment for disability, long-term sick leave and daily allowance, disability status and allowance.

Data analysis plan

The statistical analysis will be performed using the SAS software (latest current version), following a detailed statistical analysis plan.The following analyses will be performed according to the treatment group at index date for all patients and according to naïve non-naïve status of patients :- Description of baseline characteristics, with standardised difference before and after adjustment on potential confounding defined above- hdPS will be calculated using a logistic regression model taking into account information defined above- Description of primary outcome adjusted on potential confounding defined above- Description of the follow-up and drug exposure duration, as well as MS drug use - Description of the switch to another MS treatment, according the occurrence of a relapse or not- Description of healthcare resources use for MS and their related costs during the follow-up

Data management

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

No