Patient real-world clinical, neurological, tolerability, and safety outcomes for Tecfidera® and Rebif®: A retrospective study (PROTRACT)

First published: 03/03/2016

Last updated: 23/10/2018

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/26260

EU PAS number

EUPAS12652

Study ID

26260

DARWIN EU® study

No

Study countries

Canada

United States

Study description

The purpose of this study is to evaluate the proportion of patients who demonstrate nomedical need to discontinue therapy among DMT-naïve patients with relapsing forms ofmultiple sclerosis after 1 year of treatment with Rebif 44 mcg tiw or with Tecfidera 240 mg bidbased on real-world data.

Study status

Finalised

Research institutions and networks

Institutions

Real World Evidence Solutions, IMS Health

France

First published: 06/09/2011

Last updated: 20/08/2024

Institution | Other

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Gabriele Haas

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/08/2015

Actual: 27/10/2015

Study start date

Planned: 18/02/2016

Actual: 02/03/2016

Date of final study report

Planned: 30/04/2017

Actual: 20/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

EMD Serono

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:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Secondary use of data

Main study objective:

The primary objective is to evaluate the proportion of patients who demonstrate no medicalneed to discontinue therapy among Disease Modifying Therapy

(DMT)-naïve patients withrelapsing forms of Multiple Sclerosis (MS) after 1 year of treatment with Rebif 44 mcg tiw orwith Tecfidera 240 mg bid.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

REBIF

TECFIDERA

Medical condition to be studied

Relapsing-remitting multiple sclerosis

Population studied

Short description of the study population

Patients who demonstrate no medical need to discontinue therapy among DMT-naïve patients with relapsing forms of multiple sclerosis after 1 year of treatment with Rebif 44 mcg tiw or with Tecfidera 240 mg bid.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Special population of interest

Other

Special population of interest, other

Relapsing-remitting multiple sclerosis patients

Estimated number of subjects

500

Study design details

Outcomes

The primary outcome is "No medical need to discontinue therapy" defined as:1. No Evidence of Disease Activity (NEDA-2): A composite measure of (1) absence ofrelapses AND (2) no new or enlarging T2 or T1 gadolinium-enhancing lesions on MagneticResonance Imaging over the follow-up period.2. No discontinuation due to disease activity, tolerability, or adverse events during thefollow-up, Evaluation of:1. Clinical and/or neurological differences (e.g. relapses, neurological lesions) between thetwo treatment groups.2. Proportion of individuals within each treatment group who discontinued treatment due- to tolerability- to adverse events- to disease activity

Data analysis plan

observational, retrospective, longitudinal cohort study to assess effectiveness in the realworld

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Medical chart review- Retrospective data is collected through an eCRF.

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