A Retrospective Analysis in Real World on Lymphocyte Reconstitution After Lymphopenia in Patients Treated by Tecfidera and Description of Management Strategies in France (Lympho-TEC)

First published: 14/02/2021

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Study Finalised

Administrative details

EU PAS number

EUPAS39505

Study ID

47892

DARWIN EU® study

No

Study countries

☐ France

Study description

The primary objective of the study is to describe absolute lymphocyte count (ALC) reconstitution after Dimethyl fumarate (DMF) discontinuation because of lymphopenia, in Relapsing-Remitting Multiple Sclerosis (RRMS) subjects.

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: 17/12/2020

Actual: 17/12/2020

Study start date
Planned: 15/02/2021

Actual: 10/03/2021

Date of final study report
Planned: 31/01/2022

Actual: 07/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

LymphoTEC_protocol_Redacted.pdf(867.42 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Other study registration identification numbers and links

FR-BGT-11758

Link to Clinicaltrials.gov

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

The primary objective(s) of the study is to describe absolute lymphocyte count (ALC) reconstitution after Dimethyl fumarate (DMF) discontinuation because of lymphopenia, in Relapsing-Remitting Multiple Sclerosis (RRMS) Subjects.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

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

DIMETHYL FUMARATE

Medical condition to be studied

Relapsing-remitting multiple sclerosis

Population studied

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)

Estimated number of subjects

1507

Study design details

Outcomes

Time to Absolute Lymphocyte Count (ALC) Reconstitution After Dimethyl Fumarate (DMF) Discontinuation. Time From DMF Initiation to Lymphopenia Initiation and DMF discontinuation, Longitudinal evolution of ALC over time, Percentage of patients showing relapses and/or an EDSS progression, Serious Adverse events, Opportunistic or serious infections, Association between baseline demographic and clinical characteristics on the occurrence of lymphopenia and lymphocyte reconstitution.

Data analysis plan

Normality of distribution of continuous parameters will be verified by at least 2 statistical tests and visually checked. All statistical tests will be 2-sided and with a statistically significant threshold set at 5%. Missing data will be handled for the main criterion only. At least 2 different methods will be used and detailed in the SAP.

Documents

Study report

LymphoTEC_CSR Synopsis_Redacted.pdf(345.92 KB)

Data management

Data sources

Data source(s), other

EDMUS - Multiple Sclerosis

Data sources (types)

Other

Data sources (types), other

The main goal of this retrospective study with the national MS registry “OFSEP” is to describe lymphocyte reconstitution after DMF discontinuation because of lymphopenia, in RRMS patients. This study could potentially contribute to describe management strategies in France and to identify clinical risk factors predisposing for lymphopenia in patients treated by DMF.

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