Long-term surveillance of patients with multiple sclerosis to report progressive multifocal leukoencephalopathy and other serious opportunistic infections among patients treated with natalizumab

First published: 03/02/2022

Last updated: 15/02/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45446

EU PAS number

EUPAS45445

Study ID

45446

DARWIN EU® study

No

Study countries

Czechia

Study description

The primary objective of the study is to estimate the incidence of progressive multifocal leukoencephalopathy (PML) and serious adverse events (SAEs) of other opportunistic infections (OIs) among all subjects taking natalizumab.

Study status

Ongoing

Research institutions and networks

Institutions

Biogen

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Study Director Biogen

Study contact

ctrr@biogen.com

Primary lead investigator

Study Director Biogen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/10/2019

Actual: 10/12/2019

Study start date

Planned: 01/01/2019

Actual: 01/01/2019

Date of final study report

Planned: 30/04/2025

Sources of funding

- EU institutional research programme
- Other

More details on funding

Biogen

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

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 of the study is to estimate the incidence of progressive multifocal leukoencephalopathy (PML) and serious adverse events (SAEs) of other opportunistic infections (OIs) among all subjects taking natalizumab.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

NATALIZUMAB

Medical condition to be studied

Multiple sclerosis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

600

Study design details

Outcomes

Number of Subjects With Progressive Multifocal Leukoencephalopathy (PML) who are Taking Natalizumab, Number of Subjects With Serious Adverse Events (SAEs) of Other Opportunistic Infections (OIs) who are Taking Natalizumab. Number of Subjects: With SAEs, With SAEs Among Subject Subgroups Defined by Demographic and Clinical Factors, With Malignancies who are Taking Natalizumab, With Hypersensitivity Reactions who are Taking Natalizumab, Who are John Cunningham Virus (JCV) Positive and Taking Natalizumab, Who are Pregnant and Breastfeeding and Who Were Previously Exposed to Natalizumab.

Data analysis plan

Categorical variables will be summarised numerically and as rate by each category. Continuous variables will be summarised as mean ± standard deviation (SD), median, minimum and maximum.

Data management

Data sources

Data source(s), other

National MS registry ReMuS Czechia

Data sources (types)

Other

Data sources (types), other

The aim of the study is to characterise the safety profile of natalizumab in a routine clinical practice in the Czech Republic by monitoring serious adverse events (SAEs).

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