An Observational Study Utilising Data from EU National MS Registries to Estimate the Incidence of Anti-Natalizumab Antibody Among Patients Who Receive Subcutaneous Administration of Natalizumab for Treatment of RRMS

First published: 22/06/2023

Last updated: 22/08/2024

Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105827

EU PAS number

EUPAS48753

Study ID

105827

DARWIN EU® study

No

Study countries

☐ Czechia

☐ Denmark

Study description

A Study Utilising Data From European Union (EU) National Multiple Sclerosis (MS) Registries to Assess the Incidence of Anti-Natalizumab Antibody Among Participants who Receive Subcutaneous Administration of Natalizumab for Treatment of Relapsing-remitting Multiple Sclerosis (RRMS).

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: 30/06/2023

Study start date

Planned: 23/06/2023

Actual: 30/06/2023

Data analysis start date

Planned: 23/06/2023

Actual: 30/06/2023

Date of final study report

Planned: 31/12/2026

Sources of funding

- Pharmaceutical company and other private sector

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)?

EU RMP category 3 (required)

Other study registration identification numbers and links

101MS412

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 this study is to estimate the incidence of Anti-Natalizumab Antibodies (ANAs) in the cohort of natalizumab-naïve and other MS monoclonal antibody (mAb)-naive participants who start receiving natalizumab subcutaneous (SC) injections.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Name of medicine

TYSABRI

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

NATALIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG03) natalizumab

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

400

Study design details

Outcomes

- Percentage of Participants in Natalizumab-Naive and Other MS mAb-Naive Cohort who Start Taking Natalizumab Injections and Develop Anti-Natalizumab Antibodies (ANAs);
- Percentage of Participants in Natalizumab-Experienced Cohort who Switched From Natalizumab IV Infusion to SC Injection and Develop Anti-Natalizumab Antibodies (ANAs);
- Percentage of Participants With SAEs by Positive (Transient or Persistent) or Negative ANA Status;
- Percentage of Participants With MS Relapses by Positive (Transient or Persistent) or Negative ANA Status.

Data analysis plan

Descriptive analyses will be performed to characterise the study population (RRMS patients). Summary statistics such as mean and standard deviation for continuous characteristics and frequency tables for categorical characteristics will be provided.

Data management

Data sources

Data source(s), other

ReMuS: Czech National Registry of Multiple Sclerosis, Czechia

Danish MS Registry

Data sources (types)

Disease registry

Other

Data sources (types), other

It is planned that data for this study will be sourced from EU national registries. The study will initially utilize data collected from European union national MS registry (ReMuS) and Danish MS Registry.

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