TOP: Tysabri® Observational Program

First published: 29/03/2019

Last updated: 25/02/2025

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46161

EU PAS number

EUPAS28580

Study ID

46161

DARWIN EU® study

No

Study countries

- ☐ Argentina
- ☐ Australia
- ☐ Belgium
- ☐ Canada

- [ ] Czechia
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Greece
- [ ] Italy
- [ ] Mexico
- [ ] Netherlands
- [ ] Norway
- [ ] Portugal
- [ ] Slovakia
- [ ] Spain
- [ ] United Kingdom

Study description

The primary objective of this study is to assess the long-term safety and impact on disease activity and progression of natalizumab in participants with relapsing remitting multiple sclerosis (RRMS) in a clinical practice setting.

Study status

Finalised

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

Actual: 19/02/2007

Study start date

Actual: 29/06/2007

Date of final study report

Planned: 31/10/2024

Actual: 11/11/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

IMA-06-02 Protocol V9 Final 28NOV2022_Redacted.pdf(368.12 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Other study registration identification numbers and links

IMA-06-02, NCT00493298

Link to Clinicaltrials.gov

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Effectiveness study (incl. comparative)

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

The primary objective of this study is to assess the long-term safety and impact on disease activity and progression of natalizumab in participants with relapsing remitting multiple sclerosis (RRMS) in a clinical practice setting.

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

Relapsing-remitting multiple sclerosis

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

6620

Study design details

Outcomes

• Number of participants with serious adverse events (SAE)

• Annualized Relapse Rate (ARR)

• Time to first relapse

• Percentage of subjects with relapse

• Percentage of subjects with disability progression

• Percentage of subjects that reach Expanded Disability Status Score (EDSS) milestones

• Percentage of subjects whose EDSS worsened, stabilized or improved
• Evaluation of baseline disease characteristics
• Evaluation of short-term disease outcomes

Data analysis plan

All data will be summarized by presenting the frequency distributions for discrete endpoints and summary statistics (i.e. mean, standard deviation, median, and range) for continuous endpoints.

Documents

Study report

IMA-06-02 CSR Synopsis Closeout Full V1 PASS Final 11Nov2024_Redacted.pdf (326.86 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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