An observational study utilising data from the US Tysabri TOUCH programme and select EU MS Registries to estimate the risk of progressive multifocal leukoencephalopathy (PML) and other serious opportunistic infections among patients who were exposed to an MS disease modifying treatment prior to treatment with Tysabri

First published: 23/01/2018

Last updated: 24/02/2025

Study Finalised

Administrative details

EU PAS number

EUPAS19800

Study ID

48270

DARWIN EU® study

No

Study countries

☐ United States

Study description

The primary purpose of this study is to estimate the incidence of progressive multifocal leucoencephalopathy (PML) among patients who switched to Tysabri from disease modifying therapies (DMTs), including newer DMTs (including fingolimod, dimethyl fumarate and teriflunomide) and the established DMTs (interferon beta and glatiramer acetate). Researchers will also look to estimate the incidence of other serious opportunistic infections among patients who switch to Tysabri from newer DMTs (including fingolimod, dimethyl fumarate and teriflunomide) and the established DMTs (interferon beta and glatiramer acetate)

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 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: 01/12/2016

Actual: 05/12/2016

Study start date

Planned: 24/01/2018

Actual: 01/06/2017

Date of final study report

Planned: 31/12/2024

Actual: 16/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

101MS411 Protocol V2 Final 26Jan2022_Redacted.pdf (1.09 MB)

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

101MS411, Clinicaltrials.gov ID: NCT03399981, Clinicaltrials.gov URL:https://clinicaltrials.gov/ct2/show/NCT03399981?id=101ms411&rank=1

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Main study objective:

To estimate the incidence of progressive multifocal leucoencephalopathy(PML) among patients who switched to Tysabri from disease modifying therapies(DMTs), including newer DMTs(including fingolimod, dimethyl fumarate and teriflunomide) and the established DMTs(interferon beta and glatiramer acetate)

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Patient Registry Study

Study drug and medical condition

Medicinal product name

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

Progressive multifocal leukoencephalopathy

Multiple sclerosis

Population studied

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

80327

Study design details

Outcomes

To estimate the incidence of progressive multifocal leucoencephalopathy (PML) among patients who switched to Tysabri from disease modifying therapies (DMTs) and to estimate the incidence of other serious opportunistic infections among patients who switch to Tysabri from newer DMTs and the established DMTs.

Data analysis plan

Risk Estimation

Documents

Study report

101MS411 CSR Synopsis V1 PASS Final 16Sep2024_Redacted.pdf (541.13 KB)

Data management

ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

Data sources

Data sources (types)

Disease 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