JCV Antibody Program in Patients with Relapsing Multiple Sclerosis Receiving or Considering Treatment with Tysabri: STRATIFY-2

First published: 29/03/2019

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/48119

EU PAS number

EUPAS28923

Study ID

48119

DARWIN EU® study

No

Study countries

United States

Study description

The primary objective of this study is to demonstrate that the incidence of progressive multifocal Leukoencephalopathy (PML) in natalizumab-treated participants who do not have detectable antibodies to John Cunningham virus (JCV) (antibody negative) is lower than in participants who have detectable antibodies to JCV (antibody positive). The secondary objectives of this study are to: Estimate the incidence of PML in natalizumab-treated participants who are anti-JCV antibody negative and anti-JCV antibody positive, based on a meta-analysis of data obtained from this study and other data sources, Define the prevalence of anti-JCV antibody in relapsing multiple sclerosis (MS) participants receiving natalizumab within the TYSABRI Outreach: United Commitment to Health (TOUCH) Prescribing Program, Determine changes in anti-JCV antibody status over time.

Study status

Finalised

Research institutions and networks

Institutions

Biogen

First published: 01/02/2024

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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: 12/02/2010

Study start date

Actual: 31/03/2010

Date of final study report

Actual: 01/12/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

101JC402 Protocol V4 Final 28Feb13_Redacted.pdf(1.1 MB)

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

101JC402,NCT01070836

https://clinicaltrials.gov/ct2/show/NCT01070836?term=101jc402&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:

Disease epidemiology

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to demonstrate that the incidence of progressive multifocal Leukoencephalopathy (PML) in natalizumab-treated participants who do not have detectable antibodies to John Cunningham virus (JCV) (antibody negative) is lower than in participants who have detectable antibodies to JCV (antibody positive).

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, longitudinal

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

Short description of the study population

The study involved the US patients with relapsing multiple sclerosis receiving commercial Tysabri. Patients may participate in other clinical studies sponsored by Biogen Idec or Elan, however, if the anti-JCV antibody test is included in another study, they should withdraw from STRATIFY-2.

The incidence of progressive multifocal leukoencephalopathy in Tysabri-treated patients was also analysed.

Inclusion criteria:

- All patients who are enrolled and have provided at least one serum sample will be included in the analysis

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Age groups

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)

Special population of interest

Other

Special population of interest, other

Patients with progressive multifocal leukoencephalopathy

Estimated number of subjects

35895

Study design details

Outcomes

•Demonstrate that the incidence of PML in natalizumab-treated participants who do not have detectable antibodies to JC virus (JCV) (antibody negative) is lower than in patents who have detectable antibodies to JCV (antibody positive), •Estimate the incidence of PML in natalizumab-treated participants who are anti-JCV antibody negative and anti-JCV antibody positive •Define the prevalence of anti-JCV antibody in relapsing MS participants receiving natalizumab within the TOUCH Prescribing Program •Determine changes in anti-JCV antibody status over time

Data analysis plan

All appropriate background data will be summarized by presenting frequency distribution and/or basic summary statistics. The incidence of PML in patients testing anti-JCV antibody positive and in those testing, negative will be presented separately and compared using a 1-sided Fisher’s Exact Test. The percentage of patients who have tested anti-JCV antibody positive will be presented for those receiving Tysabri in the TOUCH Prescribing Program and for those who are interested in or are considering beginning Tysabri treatment. In addition, the percentage of patients who have anti-JCV antibody status changes from negative to positive over time will be presented. The data from this study will be analyzed separately and in combination with the data from the STRATIFY-1 study (Biogen Idec study 101JC401).

Documents

Study results

101JC402 CSR Synopsis V1 Section 2 Final 01Dec2016__Redacted.pdf(296.2 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