A Multicenter, Open-Label Safety Study of Natalizumab administered to Subjects with Relapsing Forms of Multiple Sclerosis who participated in STRATA

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Study Finalised

Administrative details

EU PAS number

EUPAS28992

Study ID

36709

DARWIN EU® study

No

Study countries

☐ Belgium

Study description

The primary objective for this study is long-term safety (incidence and pattern of serious adverse events) in subjects receiving natalizumab.The secondary objective is to evaluate the long-term efficacy of natalizumab in delaying the progression of disability, reducing the frequency of relapses, decreasing the disease activity observed by magnetic resonance imaging (MRI), and the evaluation of the quality of life and cognitive function in patients on treatment with natalizumab for more than 8 years.

Study status

Finalised

Research institutions and networks

Institutions

Biogen

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Institution

Multiple centres: 4 centres are involved in the study

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

Actual: 08/10/2014

Study start date

Actual: 10/12/2014

Date of final study report

Actual: 05/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen

Study protocol

BEL-TYS-14-10675_Tysabri_Protocol_11Aug14_final6811801528117131664_Redacted.pdf (2.35 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Non-EU RMP only

Other study registration identification numbers and links

BEL-TYS-14-106752014-003669-97 https://www.clinicaltrialsregister.eu/ctr-search/search?query=bel-tys-14-10675

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

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective for this study is long-term safety (incidence and pattern of SAEs) in patients receiving natalizumab. The primary objective is to evaluate the safety of natalizumab in patients with Relapsing Forms of Multiple Sclerosis who were included in STRATA and did not meet reimbursement criteria upon termination of STRATA.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Prospective, non-interventional, multicenter, open label long-term safety study

Study drug and medical condition

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

NATALIZUMAB

Medical condition to be studied

Relapsing-remitting multiple sclerosis

Population studied

Short description of the study population

Patients with relapsing-remitting Multiple sclerosis (MS) who participated in STRATA, had stable disease for at least 7 years during STRATA, and did not meet reimbursement criteria for Tysabri® in Belgium, upon termination of the STRATA study.

Inclusion Criteria:

1. Had the ability to understand the purpose and risks of the study and provided signed and dated informed consent and any authorizations required by local law in accordance with national and local subject privacy regulations.

2. Had participated in the STRATA study, had stable disease and did not meet reimbursement criteria for natalizumab (Tysabri®) in Belgium, upon termination of the STRATA study.

3. Were ≥18 years old.

4. Patients of child bearing potential had to practice effective contraception during the study and be able to continue contraception for 3 months after their last infusion.

Exclusion Criteria:

1. Patients participating in STRATA who were in line with current Belgian reimbursement criteria when they started in one of the feeder studies (Affirm or Sentinel). 2. Patients with any significant change in clinical status that, in the

opinion of the Investigator, would have made them unsuitable to participate in this study. The Investigator had to review the patient’s medical fitness for participation and consider any diseases that would have precluded treatment.
3. Patients that were unwilling or unable to comply with study requirements, or were deemed unsuitable for study participation as determined by the Investigator. 4. Female patients who were considering becoming pregnant while in the study.
5. Female patients of childbearing potential who were not using the appropriate contraception as determined by the Investigator.
6. Female patients who were currently pregnant or breastfeeding.
7. Any prescheduled elective procedure during the study period that, in the opinion of the Investigator, would have interfered with study parameters.
8. Any other condition, clinical finding, or reason that, in

Age groups

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

Multiple sclerosis patients

Estimated number of subjects

10

Study design details

Outcomes

• The primary endpoint of the open label study is the incidence of AEs and SAEs. • Disability progression • MS disease activity • JCV status • Frequent MRI monitoring • Quality of life measurement by EQ-5D • Cognitive evaluation by Symbol Digit Modalities Test (SDMT)

Data analysis plan

The purpose of this study is to evaluate the safety and efficacy of natalizumab in patients with Relapsing Forms of Multiple Sclerosis who were included in STRATA and did not meet reimbursement criteria upon termination of STRATA. The study will also evaluate the long-term effectiveness of natalizumab in delaying the progression of disability, reducing the frequency of relapses, and MRI activity during long-term treatment with natalizumab. Quality of Life measurements and cognitive evaluations will be measured on a 6-monthly basis.

Documents

Study results

BEL-TYS-14-10675_CSR Synopsis_10 Aug 2020.pdf(400.95 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