German Tysabri-Data-Register (Tysabri-Register)

First published: 08/12/2014

Last updated: 10/03/2021

Study Ongoing

Administrative details

EU PAS number

EUPAS7193

Study ID

39827

DARWIN EU® study

No

Study countries

Germany

Study description

The development of immune therapies during the last two decades has focused attention on the appropriate and indication-based usage of the different available treatments by weighting clinical presentation, benefits versus risks

and costs. Reliable data on the long-term safety and effectiveness of approved therapies from routine clinical care are not available at the time of drug approval due to known limitations of phase-3 studies, such as certain in- and exclusion criteria, and short or moderate follow-up periods. For the assessment of the incidence, type and characteristics of adverse events in patients treated with Natalizumab in routine clinical care the KKNMS established a therapy register "Tysabri-Register".

Study status

Ongoing

Research institutions and networks

Institutions

Institute of Epidemiology and Social Medicine

First published: 01/02/2024

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Institution

Networks

Disease-oriented Competence Network Multiple Sclerosis

Contact details

Study institution contact

Klaus Berger bergerk@uni-muenster.de

Study contact

bergerk@uni-muenster.de

Primary lead investigator

Klaus Berger

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 26/06/2014

Study start date

Actual: 01/10/2014

Date of final study report

Planned: 26/12/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Biogen Idec GmbH

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The primary objective of the German Tysabri-Data-Register is to examine the long-term safety profile of Tysabri in heterogeneous groups of MS patients. Secondary objective is to identify risk factors (baseline disease characteristics) for adverse events which might act as potential prognostic indicators.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational multicenter register (NIS)

Study drug and medical condition

Medical condition to be studied

Multiple sclerosis

Population studied

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)

Estimated number of subjects

1.830

Study design details

Outcomes

The primary outcome the incidence, type and characteristics of adverse events in MS patients treated with Tysabri in routine clinical care. For the secondary objective the following factors will be evaluated: a) EDSS progressionb) Annual relapse rate.

Data analysis plan

All adverse events (AEs) will be assessed prospectively. Safety will be monitored by estimating the cumulative incidence overall and stratified by type of disease severity. Type, severity of AEs, and proportion of patients experiencing multiple AEs (more than one AE) will be examined using descriptive statistics. Potential risk factors of AE occurrence will be identified by subgroup analyses (e.g. stratified by age, gender, medical history of MS therapies, disease duration, comorbidities, EDSS). Multiple adjustments will be done by logistic regression. All SAEs will be reported to the manufacturer immediately after becoming aware. The manufacturer will subsequently report to the regulating authority.Data on adverse events (non-serious AE) and effectiveness of Tysabri therapy will be analyzed every six month (6-month Interim analyses) and reported.

Documents

Study publications

Simbrich A, Thibaut J, Khil L, Maximov S, Wiendl H, Berger K for the REGIMS Inv…

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.

Conflicts of interest of investigators

ENCePP-Conflict-of-interest-Tysabri-Data-Register.pdf (209.67 KB)

Signed code of conduct

DoC ENCePP Code of Conduct_7193.pdf (64.54 KB)

Signed code of conduct checklist

Checklist of ENCePP CoC for ENCePP Studies_7193.pdf (281.69 KB)

Signed checklist for study protocols

Checklist for Study Protocol_7193.pdf (387.68 KB)

Data sources

Data sources (types)

Disease registry

Other

Data sources (types), other

Spontaneous reporting system, 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