An immune therapy register for the improvement of drug safety and treatment of patients with Multiple Sclerosis (REGIMS)

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Study Planned

Administrative details

EU PAS number

EUPAS7892

Study ID

29641

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 an immune therapy except Natalizumab in routine clinical care the KKNMS established a "immune therapy register for the improvement of drug safety and treatment of patients with Multiple Sclerosis" (REGIMS).

Study status

Planned

Research institutions and networks

Institutions

Institute of Epidemiology and Social Medicine

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Institution

Networks

Disease-oriented Competence Network Multiple Sclerosis

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Klaus Berger

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/01/2013

Study start date

Planned: 01/01/2014

Data analysis start date

Planned: 01/01/2015

Date of final study report

Planned: 30/12/2019

Sources of funding

- Other

More details on funding

BMBF

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 REGIMS is to examine the long-term safety profile of immune therapies 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

3.140

Study design details

Outcomes

The primary outcome the incidence, type and characteristics of adverse events in MS patients treated with an immune therapies 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 beidentified 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 Paul Ehrlich Institute (PEI). Data on adverse events (non-serious AE) and effectiveness of Tysabri therapy will beanalyzed every six month (6-month

Interim analyses) and reported.

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

Spontaneous reports of suspected adverse drug reactions

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