Prospective Cohort Study of Long-Term Safety of Teriflunomide in Multiple Sclerosis Patients in Europe (OBS12573)

First published: 22/06/2017

Last updated: 27/10/2021

Study Finalised

Administrative details

EU PAS number

EUPAS19610

Study ID

43828

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Denmark
- ☐ France
- ☐ Italy

Norway

Study description

Teriflunomide is an immunomodulator with both anti proliferative and anti inflammatory activity that has shown to be effective in remitting-relapsing forms of Multiple Sclerosis (MS). In order to further evaluate the long-term risks of teriflunomide, a five year post-approval observational study is proposed to investigate the incidence of selected safety events and overall safety in patients treated with teriflunomide in Europe in real life.

Study status

Finalised

Research institutions and networks

Institutions

International Prevention Research Institute (IPRI)

France

First published: 19/03/2010

Last updated: 05/04/2012

Institution | **EU Institution/Body/Agency** | **ENCePP partner**

BELTRIMS (Belgian MS registry) Brussels, Belgium, Hospices Civils de Lyon (French Systeme National des données de Santé) Lyon, France, Danish MS

Registry Copenhagen, Denmark, AIM-IMA (Belgian social security agencies) Brussels, Belgium

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Peter Boyle

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 15/10/2015

Study start date

Actual: 26/08/2013

Date of final study report

Planned: 31/12/2020

Actual: 02/07/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

SANOFI

Study protocol

Amended_Protocol_EUPASS19610_20191127.pdf(425.83 KB)

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)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Combined primary data collection and secondary use of data

Main study objective:

To characterize the long term safety profile of teriflunomide and determine the incidence of adverse events of special interest (AESI) in a real life setting. These include acute liver injuries, infections (included opportunistic), interstitial lung disease and pancreatic effects, cancers, cardiovascular events.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L04AA31) teriflunomide

teriflunomide

Medical condition to be studied

Relapsing-remitting multiple sclerosis

Population studied

Short description of the study population

MS patients treated and not treated with teriflunomide identified in a pooled analysis of national Multiple Sclerosis registries.

Inclusion criteria.

• All Patients with a diagnosis of MS ;

• Aged 18 years or more at the date of entry in the cohort;

• registered in a MS registry database (as noted in section I9);

• treated with a Disease Modifying Therapy during the study period;

• patients who provide written consent (if appropriate and in accordance with local law)

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

Relapsing-remitting multiple sclerosis patients

Estimated number of subjects

15000

Study design details

Data analysis plan

The analysis consists in three major parts:The primary analysis will describe the population of subjects treated with teriflunomide and subjects treated with other DMT. This part will be essentially descriptive.The secondary analyses will consist in computing incidence rates and 95% confidence intervals of adverse events of special interest listed in the protocol, and to evaluate whether teriflunomide treated is associated with an increased risk of any of the AESI compared with other DMT. This requires computation of person-years.The exploratory analyses will be more detailed analyses to evaluate identified risks of adverse events in teriflunomide patients compared to groups of patients with similar characteristics. These analyses will be carried out only if the following conditions are fulfilled for a given AESI:- Statistically significant associations are found in the pooled results - Absence of heterogeneity in the pooled results

Documents

Study results

Summary of Study report_20211025.pdf(95.46 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 source(s)

Danish registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Disease registry

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