A prospective, open-label, multicenter, single-arm observational registry to describe adherence in relapsing remitting multiple sclerosis patients being prescribed teriflunomide (Aubagio®) in Belgium in routine clinical practice. (AUBADHE)

First published: 17/01/2019

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS27536

Study ID

48859

DARWIN EU® study

No

Study countries

Belgium

Study description

Product observational registry to describe adherence in terms of persistence and continuation rate during the first 18 months in patients who take Aubagio® in a real life setting, and To describe adherence in terms of initiation and implementation To describe the reasons for treatment discontinuation To describe the drivers of adherence To assess the evolution of fatigue, depression and cognition in patients taking Aubagio® and their impact on adherence The study is non-interventional. Patients will be prescribed Aubagio® according to local label and reimbursement criteria, independently from the decision to include the patient in the registry. Patients fulfilling the study criteria will be asked to participate in this study. Duration of treatment: the registry observation period will last until the termination of the treatment or maximum 18 months, whichever comes first. Patients will continue on medication as long as this treatment is considered appropriate for this patient independently from the registry. Data will be collected at inclusion (baseline visit), after 3 months and every 6 months after inclusion (according to general clinical practice) or as planned according to clinical practice. An additional checkpoint for adherence (phone call) will be planned 2 weeks after inclusion.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 17 centres are involved in the study

Contact details

Study institution contact

Vanina Belis vanina.belis@sanofi.com

Study contact

vanina.belis@sanofi.com

Primary lead investigator

Vincent Dr van Pesch

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/03/2017

Actual: 17/01/2019

Study start date

Planned: 28/08/2018

Actual: 17/01/2019

Data analysis start date

Planned: 30/03/2021

Date of interim report, if expected
Planned: 30/03/2021

Date of final study report
Planned: 12/01/2022

Actual: 02/09/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi Belgium

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

TERIFL08913 - AUBADHE

Methodological aspects

Study type

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

To describe adherence in terms of persistence and continuation rate during the first 18 months in patients who take Aubagio® in a real life setting.

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Prospective, open-label, multicenter, single-arm observational registry

Study drug and medical condition

Medicinal product name

AUBAGIO

Medical condition to be studied

Multiple sclerosis

Population studied

Short description of the study population

Adult patients aged 18 years or older diagnosed with relapsing remitting multiple sclerosis receiving treatment with teriflunomide (Aubagio) included from 1st
of November 2019 and were followed-up to 12 months or treatment termination, whichever came first under the routine clinical practice.
Inclusion criteria:
• Aubagio was prescribed to the patient independently from the decision to include the patient in the registry
• Patient was prescribed Aubagio according to reimbursement criteria in Belgium:
a) Adult patients (>18 years old)
b) Patients suffering from RRMS diagnosed using the most recent version of the McDonald criteria
c) Expanded Disability Status Scale (EDSS) score ≤ 6.5
• Patient understood and signed informed consent form
• Patient did not have the first intake of Aubagio at the time of inclusion visit yet

Exclusion criteria:

• Patient presenting a contraindication according to the local label.
• Prior treatment with Aubagio
• Participation to an Aubagio Patient Support Program (PSP).

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

Patients with multiple sclerosis

Estimated number of subjects

120

Study design details

Outcomes

To describe adherence in terms of: - Persistence during the first 18 months in patients who take Aubagio® in a real life setting - Continuation rate in patients taking Aubagio® at 18 months based on refill data and and modified BAASIS questionnaire, Secondary endpoints will describe adherence in terms of initiation, implementation and persistence at different time points according to the prescription renewal dates and/or the modified BAASIS questionnaire.

Drivers and barriers to adherence will be evaluated, as well as disease-related factors, such as fatigue, depression and cognition

Data analysis plan

The statistical analysis will be performed using SAS v9.4. statistical software. The approach to the statistical analyses in this project will be descriptive in nature. Continuous data will be described by their mean, standard deviation, median, minimum and maximum. All summaries will be presented on all available data. Categorical data will be described by the number and percentage of subjects in each category. Missing observations will be presented in tables as a separate category. The calculation of proportions will not include the missing category. In addition to descriptive statistics for the primary, secondary, and exploratory outcome variables, subgroup evaluations may be performed. Subgroups of interest may be defined by baseline demographics, treatment experience, site characteristics and levels of fatigue and/or cognition and/or depression. Inferential statistics will also be used to potentially compare the subgroups. To be continued.

Documents

Study results

TERIFL08913_AUBADHE_CSR_final_12JAN2022_Review form - signed.pdf (1.48 MB)

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)

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