Behavior and knowledge survey to assess the effectiveness of educational materials in patients treated with AUBAGIO® (teriflunomide) (cross-sectional survey)

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Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS31883

Study ID

35671

DARWIN EU® study

No

Study countries

Belgium

France

Germany

Greece

Italy

Netherlands

Spain

United Kingdom

Study description

The objective of the survey is to assess descriptively knowledgeand behavior of treated patients about the educational materialsand thus the effectiveness of these materials and tools to ensurethe safe use of Aubagio®.Research questions:1. Has the patient received the Patient Card?2. What is the knowledge of patients about the Patient Card (PC)?3. What is the knowledge of patients about the risks associated with the use of Aubagio®?4. Does patients' self-report indicate that they are undertaking risk minimization behavior (contraception, compliance with blood monitoring)?

Study status

Finalised

Research institutions and networks

Institutions

Sanofi

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Institution

Contact details

Study institution contact

Trial Transparency Team Trial Transparency Team contact-us@sanofi.com

Study contact

contact-us@sanofi.com

Primary lead investigator

Trial Transparency Team Trial Transparency Team

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 05/01/2016

Study start date

Actual: 01/03/2016

Date of final study report

Actual: 21/03/2019

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

TERIFC09617_Wave 1 - protocol patient - Aubagio.pdf (132.23 KB)

TERIFC09617_Wave 2 - protocol patient - Aubagio.pdf (314.35 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)

Other study registration identification numbers and links

TERIFC09617

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Knowledge and behavior of treated patients

Data collection methods:

Primary data collection

Main study objective:

The objective of the study is to assess descriptively knowledge and behavior of treated patients about the items of the educational materials and thus the effectiveness of these materials and tools to ensure the safe use of Aubagio®.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Medicinal product name

AUBAGIO

Population studied

Short description of the study population

The population for this study will be a randomly generated sample of patients treated for Multiple Sclerosis (MS) with Aubagio. To have wide coverage of patients across the European Union (EU), the survey will be conducted in at least 5 countries of the EU. The registered patient population will be described in terms of age, year of first diagnosis and gender and compared in each participating country with the known MS population statistics.

Inclusion criteria

1. Patient is being treated with Aubagio at study entry
2. Patient supplies informed consent by ticking a box on the survey website

Exclusion criteria

1. For Wave 2 only: patient completed the survey in Wave 1
2. Patient has not been prescribed Aubagio.

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

0

Study design details

Outcomes

Knowledge is defined as awareness and understanding of important risk minimization information contained in the PIL and PC. Behavior is defined as report of appropriate risk minimization behavior. Appropriate risk minimization behavior is measured.

Data analysis plan

Primary analysisThe analysis will be descriptive (e.g. frequency distributions for each item). The response on knowledge and behavior is considered satisfactory if participants provide >70% of correct answers.Secondary analysisThe analysis will be descriptive.1. Where knowledge or behavior is found to be <100% a more detailed analysis will be conducted (e.g. to identify specific areas where knowledge is low).2. Responses in subgroups compared to the rest of the sample. Subgroups to be analyzed include: country, childbearing potential, having read the RMP materials, time since prescription with Aubagio®.3. Comparison of age and time since diagnosis of the sample from each participating country with known MS population statistics in participating countries as a gauge of the representativeness of the sample.

Documents

Study results

Aubagio Patients Wave 1 and 2 combined report-Final.pdf (534.79 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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection, Data will be collected via patient self-reports in the online questionnaire.

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