Knowledge survey to assess the effectiveness of educational materials among patients prescribed LEMTRADA® (alemtuzumab)

First published: 29/05/2020

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS35552

Study ID

35661

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Denmark
- ☐ Germany

- [ ] Greece
- [ ] Italy
- [ ] Netherlands
- [ ] Norway
- [ ] Spain
- [ ] United Kingdom

Study description

The objective of the survey is to assess descriptively the knowledge of treated patients about the key educational messages concerning autoimmune conditions and serious infections, and adherence to monitoring, to ensure the safe use of LEMTRADA. Research questions:1. Has the patient received the patient guide (PG) and patient alert card (PAC)?2. What is the knowledge of patients about the PG and PC?3. What is the knowledge of patients about the risks associated with the use of LEMTRADA?4. What is the knowledge of patients about risk minimization activities to be undertaken?

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

Planned: 01/12/2015

Actual: 05/01/2016

Study start date

Planned: 01/12/2015

Actual: 01/03/2016

Data analysis start date

Planned: 02/02/2016

Actual: 02/08/2016

Date of interim report, if expected

Planned: 01/03/2016

Actual: 01/11/2016

Date of final study report
Planned: 07/11/2017

Actual: 06/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

ALEMLC09615_2015-11-30 LEMTRADA_Patients_PROTOCOL 1 7 -WAVE1-final.pdf(666.14 KB)

ALEMLC09615_2017-05-08 LEMTRADA_Patients_PROTOCOL 1.8 - WAVE 2.pdf (101.32 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

ALEMLC09615

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)

Data collection methods:

Primary data collection

Main study objective:

The objective of the survey is to assess descriptively the knowledge of treated patients about the key educational messages concerning autoimmune conditions and serious infections, and adherence to monitoring, to ensure the safe use of LEMTRADA.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Name of medicine

LEMTRADA

Population studied

Short description of the study population

Patients prescribed Lemtrada.

Inclusion criteria

• Patient has been diagnosed with Multiple Sclerosis (MS)

• Patient has been prescribed at least one dose of Lemtrada

• Patient supplies informed consent by ticking a box on the website.

Exclusion criteria

• Patient completed the survey in Wave 1

• Patient has not been prescribed Lemtrada.

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

Awareness of patient educational materials, knowledge about SAEs and signs and symptoms related to LEMTRADA, and knowledge of risk minimization activities. Comparisons of patient knowledge at the country level.

Data analysis plan

Descriptive analyses including the number and percentage of patients that demonstrated knowledge and awareness of educational materials.

Documents

Study results

riskmgtsystem-patient-survey-report.pdf(3.75 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

The questionnaire collected data concerning patient familiarity with educational materials.

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