Knowledge survey to assess the effectiveness of educational materials among healthcare professionals who prescribe Lemtrada® (alemtuzumab)

First published: 29/05/2020

Last updated: 14/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS35547

Study ID

35666

DARWIN EU® study

No

Study countries

- ☐ Belgium
- ☐ Denmark
- ☐ Germany

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

Study description

The overall objective of the survey is to assess descriptively the knowledge level of Healthcare Professionals (HCPs) with regard to educational messages and thus the effectiveness of the educational materials to support the safe use of LEMTRADA:Research questions:1. What is the HCP's understanding and awareness of the risks associated with use of LEMTRADA?2. What is the HCP's knowledge of the key safety messages in the content of the HCP guide and HCP checklist?3. What is the HCP's knowledge and understanding of the risk minimization activities to be undertaken in relation to LEMTRADA?

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: 01/02/2016

Actual: 01/08/2016

Date of interim report, if expected

Planned: 07/03/2016

Actual: 07/11/2016

Date of final study report
Planned: 06/11/2017

Actual: 05/11/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi

Study protocol

ALEMLC09614_2015-11-30 LEMTRADA_HCP_PROTOCOL 1 7-WAVE 1-final.pdf
(523.19 KB)

ALEMLC09614_2017-05-08 LEMTRADA_HCP_PROTOCOL 1.8 - WAVE2-2.pdf
(113.22 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

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 overall objective of the survey is to assess descriptively the knowledge level of Healthcare Professionals (HCPs) with regard to educational messages and thus the effectiveness of the educational materials to support 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

Healthcare Professional (HCPs) involved in the treatment of MS using Lemtrada.

Inclusion criteria

• HCP is a neurologist/MS specialist

• HCP has prescribed Lemtrada to at least one patient within the past 6 months

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

Exclusion criteria

• HCP has not prescribed Lemtrada within the past 6 months

• Participation in the questionnaire in Wave 1.

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

0

Study design details

Outcomes

Awareness of HCP and patient educational materials, knowledge of the key points of the educational materials. Subgroup comparisons based on country and specialist role.

Data analysis plan

Descriptive statistics including HCP understanding and awareness of educational materials at 18 and 36 months after the launch of Lemtrada.

Documents

Study results

riskmgtsystem-hcp-survey-report.pdf(4.1 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Cross-sectional data were collected on HCP characteristics.

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