A non-interventional post-authorisation safety study to investigate drug utilisation and safety monitoring patterns for Lemtrada (alemtuzumab)

First published: 26/08/2021

Last updated: 06/05/2025

Study Finalised

Administrative details

EU PAS number

EUPAS42540

Study ID

50553

DARWIN EU® study

No

Study countries

- [ ] Belgium
- [ ] Czechia
- [ ] Germany

United Kingdom

Study status

Finalised

Research institutions and networks

Institutions

Parexel International

United States

First published: 19/10/2010

Last updated: 10/12/2024

Institution | **Non-Pharmaceutical company** | **ENCePP partner**

Czech MS Registry Czech Republic, AIM-IMA Belgium, MS Center Dresden, Center of Clinical Neuroscience Germany, University Hospital of Wales UK, Cambridge University Hospitals UK, Derriford Hospital/ Plymouth University UK

Contact details

Study institution contact

Pharmacoepidemiology lead Patient Safety and Pharmacovigilance Contact-US@sanofi.com

Study contact

Contact-US@sanofi.com

Primary lead investigator

Katja M Hakkarainen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 19/10/2020

Actual: 19/10/2020

Study start date

Planned: 01/04/2021

Actual: 15/11/2021

Data analysis start date

Actual: 12/09/2022

Date of interim report, if expected

Planned: 31/12/2022

Actual: 29/11/2022

Date of final study report

Planned: 30/09/2024

Actual: 09/09/2024

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Sanofi Genzyme

Study protocol

alemtuzumab-lemtrada-dus-pass-protocol-may-2021_Redacted.pdf(1.77 MB)

lemtrada-dus-pass-amended-protocol-V3.1-Final_clean version_12-Dec-2023_comments removed_redacted.pdf(2.12 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Main study objective:

1a) to measure the proportion of patients who meet the newly restricted indication on initiating their first course of LEMTRADA after implementation of the revised EU SmPC January 2020
1b) to measure the proportion of LEMTRADA courses, first or continuing, that are not contraindicated after implementation of revised SmPC January 2020

Study drug and medical condition

Name of medicine

LEMTRADA

Study drug International non-proprietary name (INN) or common name

ALEMTUZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L04AG06) alemtuzumab
alemtuzumab

Medical condition to be studied

Multiple sclerosis

Population studied

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

120

Study design details

Data analysis plan

In each individual data source, descriptive proportions will be calculated as:

• Proportion of new LEMTRADA users prescribed in accordance with the newly revised indication (numerator = # patients with revised indication, denominator = all patients initiating their first course of LEMTRADA after implementation of the revised EU SmPC in 01/2020).

• Proportion of new or continuing LEMTRADA users without any contraindications at time of course initiation after 01/2020 (numerator = # courses without contraindications, denominator = all LEMTRADA courses post 01/2020)

• Proportion of LEMTRADA users receiving advised cardiac monitoring (ECG/HR/BP) and blood testing prior to, HR/BP during, and platelet testing during LEMTRADA course (numerator = # courses with each unique test prior to and during infusion, denominator = all LEMTRADA courses post 01/2020)

Additionally, percentage adherence to each long-term test will be calculated at patient level for up to 48 months since last infusion.

Documents

Study results

alemtuzumab-lemtrada-dus(dut0008)final-report-abstract.pdf(804.97 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)

Administrative healthcare records (e.g., claims)

Disease registry

Electronic healthcare records (EHR)

Use of a Common Data Model (CDM)

CDM mapping

Yes

CDM Mappings

CDM name

OMOP

CDM website

https://www.ohdsi.org/Data-standardization/

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

Unknown