A Cross-sectional Survey to Evaluate Patient Knowledge of Safety Messages Included in the Patient Safety Brochure and Patient Alert Card for IMLYGIC®

First published: 12/12/2019

Last updated: 24/02/2022

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/45945

EU PAS number

EUPAS31213

Study ID

45945

DARWIN EU® study

No

Study countries

☐ Germany

☐ Netherlands

Study description

The overall objective of this study is to evaluate awareness of the IMLYGIC PEB and knowledge of the key messages included in the IMLYGIC PEB among physicians who completed the required IMLYGIC training.

Study status

Finalised

Research institutions and networks

Institutions

Amgen

☐ United States

First published: 01/02/2024

Last updated: 21/02/2024

Institution

Multiple centres: 12 centres are involved in the study

Contact details

Study institution contact

Global Development Leader Amgen Inc.

Study contact

medinfo@amgen.com

Primary lead investigator

Global Development Leader Amgen Inc.

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 11/07/2018

Actual: 11/07/2018

Study start date

Planned: 30/04/2021

Actual: 01/04/2021

Data analysis start date

Planned: 08/11/2021

Actual: 27/09/2021

Date of final study report

Planned: 01/03/2022

Actual: 23/02/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Amgen

Study protocol

20180062_01.02.06 Public Redacted Protocol Ver 1.0 2019-10-14 English.pdf
(4.7 MB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective is to evaluate patients’ knowledge levels of the key messages included in the IMLYGIC Patient Safety Brochure among patients who receive IMLYGIC.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XX51) talimogene laherparepvec

talimogene laherparepvec

Medical condition to be studied

Malignant melanoma stage III

Population studied

Short description of the study population

The target population is patients who receive IMLYGIC in Germany and the Netherlands.

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

50

Study design details

Outcomes

The primary endpoints are the percentages of patients with correct responses to the knowledge-related questions. Success criteria for the primary endpoint percentages are at least 60% of patients provide a correct response to each individual knowledge-related question that has a minimum n = 30. The secondary endpoints are the percentages of patients that report receiving, reading, and using the IMLYGIC Patient Safety Brochure and Patient Alert Card.

Data analysis plan

The primary analysis population will include all patients who have completed at least 1 of the endpoint questions in the survey. Frequencies, percentages, and corresponding 95% confidence intervals (CIs) will be used to summarise the endpoints for the primary analysis set overall, by country, and by subgroups. For each knowledge level question, the percentage of patients who answer each

question correctly will be estimated and assessed against the 60% (± 95% CI) target. For secondary endpoints, percentages and 95% CI will be estimated. The primary analysis will be performed by having read vs. not read the IMLYGIC Patient Safety Brochure. An analysis to evaluate the impact of recall bias will be performed by repeating the primary analysis stratified by tertiles of time since patients first received IMLYGIC to when they completed the survey.

Documents

Study results

01.47.01.01 20180062 Observational Research Study Report Published Report Abstract_Redacted.pdf(1.01 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Patient Survey

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