Injectors’ Survey to Assess Effectiveness of BELKYRA Risk Minimisation Activities

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Study Finalised

Administrative details

EU PAS number

EUPAS24321

Study ID

36555

DARWIN EU® study

No

Study countries

- Bulgaria
- Italy
- Lithuania
- Spain
- Sweden
- United Kingdom

Study description

This study will assess HCPs understanding of the key safety messages of BELKYRA regarding injection site nerve injury and injection site skin ulceration as communicated in the Injector’s Guide for the Safe Use of BELKYRA.

Study status

Finalised

Research institutions and networks

Institutions

CRO

Contact details

Study institution contact

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Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Samantha Kimball

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 16/04/2018

Actual: 16/04/2018

Study start date
Planned: 01/06/2021

Actual: 19/10/2021

Date of final study report
Planned: 30/06/2024

Actual: 18/07/2025

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

AbbVie

Study protocol

Belkyra PASS protocol 2.0_FINAL_Redacted.pdf (975.1 KB)

belkyra-pass-protocol-v3-19apr2024_Redacted.pdf (916.01 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

CMO-EPI-FAS-0565

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)

Main study objective:

This study objective is to assess HCPs’ understanding of the key safety messages contained in the Injector’s Guide for the Safe Use of BELKYRA regarding injection site nerve injury and injection site skin ulceration

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Online Survey

Study drug and medical condition

Medicinal product name, other

Belkyra

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

150

Study design details

Outcomes

The survey will evaluate the HCPs understanding of the key safety messages of BELKYRA as outlined in the Injector’s Guide for the Safe Use of BELKYRA

Data analysis plan

• Data collected from the survey will be reported as descriptive statistics. Frequency distributions with 95% CIs will be calculated for responses to questions that address the survey objectives (i.e. excluding demographic questions).

• Survey data will also be analysed by country and speciality (if number of respondents will be sufficient).

• Data will also be analysed by countries in which the Injector’s Guide has been introduced vs. those countries that have not. Responses will be categorised as “Correct response” and “Incorrect response”

• Each question will be assessed individually

Documents

Abstract of study report

CMO-EPI-FAS-0565-Belkyra-final-study-report-Abstract.pdf (79.19 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

HCPs 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