Evaluation of Physician and Patient Knowledge of Safety and Safe Use Information for Aflibercept in Europe: An Observational Postauthorisation Study

First published: 19/06/2015

Last updated: 05/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/23134

EU PAS number

EUPAS9991

Study ID

23134

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Spain
- [ ] United Kingdom

Study description

The study will be an observational, cross-sectional study of knowledge, understanding, and self-reported behavior among a sample of physicians and patients with recent aflibercept experience in a total of up to five European countries.

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

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Institution | Not-for-profit | ENCePP partner

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Contact details

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Primary lead investigator

Elizabeth Andrews

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 20/06/2013

Actual: 20/06/2013

Study start date

Planned: 01/12/2015

Actual: 07/12/2015

Date of final study report

Planned: 15/03/2017

Actual: 05/06/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer Pharma AG

Study protocol

EM_Protocol_Final after EMA review_v3_11 Feb 2015ENCePP.pdf(961.69 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)

Methodological aspects

Study type

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to measure physician and patient knowledge and understanding of the key information contained in the aflibercept educational materials: the prescriber guide and video, and the patient booklet “Your guide to EYLEA,” patient information leaflet, and audio CD.

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(S01LA05) aflibercept

aflibercept

Population studied

Short description of the study population

Physicians and patients with recent aflibercept experience in a total of up to five European countries (the United Kingdom, Germany, France, Spain, and Italy).

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

1250

Study design details

Outcomes

1) Knowledge and understanding among physicians regarding key safety information contained in the educational materials: the prescriber guide and video2) Knowledge and understanding among patients regarding key safety information contained in the educational materials: the patient booklet “Your guide to EYLEA,” patient information leaflet, and audio CD.

Data analysis plan

Analyses will include detailed review of responses to individual questions as well as potential summary measure across logical grouping of response items. Physician results will be stratified by country and other logical variables. Patient results will be stratified by country and other logical variables, potentially including a measure of the knowledge level of their physician. A detailed

analysis plan describing methods of analysis and presentation and including table shells will be developed before analysis of data is initiated. In addition to a description of the analysis of the questionnaire data, the analysis plan will describe any planned comparisons of participants and non-participants.

Documents

Study results

16526_EU-PAS_Abstract_CTP.pdf(61 KB)

Study report

16526_Eylea Europe RMS_Final Report_Bayer_15Nov2017.pdf(6.3 MB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Cross-sectional data collection through an interviewer administered questionnaire for the patient assessment and a web-based questionnaire for the physician assessment.

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

Unknown