An Observational, Prospective Post-Marketing Surveillance Program to Evaluate theSafety Profile of Intravitreal Ozurdex® in the Treatment of Visual Impairment due to Diabetic Macular Edema by Actively Identifying and Evaluating the Occurrence of Adverse Events and Serious Adverse Events information

First published: 08/11/2016

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Study Finalised

Administrative details

EU PAS number

EUPAS16156

Study ID

23957

DARWIN EU® study

No

Study countries

India

Study description

Objectives The objective of the study is to evaluate the safety profile of Ozurdex® by actively identifying and evaluating the occurrence of AEs and SAEs for 1 year period in adult Indian patients (≥18 years of age) who will be receiving at least one intravitreal Ozurdex® injection for the treatment of visual impairment due to DME. Study design Observational, prospective post marketing surveillance (PMS) program to evaluate the safety profile of intravitreal Ozurdex® by actively identifying and evaluating the occurrence of AEs and SAEs information. Study Population Indian adult patients aged ≥18 years who receive at least on intravitreal Ozurdex injection for the treatment of visual impairment due to DME Study Sites Identification of relevant prescribing physicians that located across the country will be done. Identified prescribing physicians will be invited to participate in the study Patient Recruitment Patients of physician that have been trained on the conduct of the study will be contracted to recruit eligible patients. Patients will be enrolled in the study after informed consent and Ozurdex implanatation Sample Size Approximately 250 patients from about 20 sites in India Study Duration One year after study start date Data Collection Study physicians will fill out CRFs for each of their enrolled patients. Analysis Only descriptive data analysis will conducted.

Study status

Finalised

Research institutions and networks

Institutions

ClinTec

Contact details

Study institution contact

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Study contact

CT.Disclosures@abbvie.com

Primary lead investigator

Anita Verga

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 30/08/2016

Study start date

Planned: 30/09/2016

Actual: 05/12/2016

Date of final study report

Planned: 01/04/2018

Actual: 06/04/2018

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

Ozurdex Protocol_v 1 0_09Sep2016_Final (002).D1.pdf (155.56 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Non-EU RMP only

Other study registration identification numbers and links

1491-401-008

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

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:

To evaluate the safety profile of Ozurdex® by actively identifying and evaluating the occurrence of AEs and serious adverse events (SAEs) for 1 year period in adult Indian patients (≥18 years of age) who will be receiving at least one intravitreal Ozurdex® injection for the treatment of visual impairment due to DME.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medicinal product name

OZURDEX

Medical condition to be studied

Macular oedema

Population studied

Short description of the study population

Adult subjects who were scheduled to receive at least one intravitreal Ozurdex® injection for the treatment of visual impairment due to diabetic macular edema.

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)

Special population of interest

Other

Special population of interest, other

Patients with diabetic macular oedema

Estimated number of subjects

250

Study design details

Data analysis plan

For continuous data, number of non-missing records, mean, standard deviation, median, minimum, maximum and the two-sided 95% confidence interval (CI) of the mean will be presented. For categorical data, number of non-missing records and percentages will be presented. Frequency of AE/SAEs among the study participants during the study period will be calculated if applicable.

Documents

Study results

Ozurdex_Abstract_06Apr2018_v1.0 Redacted.pdf (117.31 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

Prospective patient-based data collection

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