# 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

**Last updated:** 02/07/2024

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**

Anita Verga CT.Disclosures@abbvie.com

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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Primary data collection

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**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

**Name of medicine**

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

## 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