Post-Authorization Safety Study of OZURDEX® (Dexamethasone Intravitreal Implant): A Prospective Observational Study to Evaluate Long-Term Safety in Real-World Clinical Practice (CONSTANCE)

First published: 13/09/2016
Last updated: 14/03/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/34210

EU PAS number
EUPAS15160

Study ID
34210

DARWIN EU® study
No

Study countries
France
Germany
Spain
United Kingdom

Study description
This is a multi-center, prospective, observational study to evaluate the long-term safety profile of OZURDEX® in adult patients diagnosed with macular oedema following CRVO or

BRVO or patients with non-infectious posterior segment uveitis, under conditions of routine medical practice in accordance with the product's Summary of Product Characteristics. The study will target recruitment of 650 patients, 500 with RVO and 150 with non-infectious posterior segment uveitis, with patients receiving >2 implants constituting at least 40% (N?260) of the study sample. As an observational study, all treatment decisions are at the discretion of the patient's health care provider and are not defined or mandated by the study design or protocol. Patients will receive OZURDEX® under routine clinical practice, and if they elect to participate in the study (i.e. provide informed consent), they will be followed for two years from study enrollment. The research objectives of this study are as follows: Primary objective: To evaluate the long-term safety of OZURDEX®, including the identified and potential risks as listed in the risk management plan, in patients with macular oedema following RVO or non-infectious posterior segment uveitis who are treated with OZURDEX® under conditions of routine medical practice. Secondary objective: To describe treatment patterns for patients receiving OZURDEX® for the treatment of macular oedema following RVO or non-infectious posterior segment uveitis in real-world clinical practice.

Study status
Finalised

Research institution and networks

Institutions

Real World & Late Phase Research (RWLPR), Quintiles

France
First published: 20/03/2015
Last updated
25/03/2015

Institution
ENCePP partner
Other

Multiple centres: 75 centres are involved in the study

Contact details

Study institution contact
Catherine Godefroy

Study contact

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Primary lead investigator
Catherine Godefroy
Primary lead investigator

Study timelines

Date when funding contract was signed
Planned:
01/01/2011
Actual:
01/01/2011

Study start date
Planned:
29/03/2012
Actual:
29/03/2012

Date of final study report
Planned:
22/09/2016
Actual:
30/09/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Allergan

Study protocol

Allergan_Ozurdex_PASS_protocol_17Jan2012_v1.6_Final_signed_Redacted.pdf(256.12 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

206207-025

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 long-term safety of OZURDEX®, including theidentified and potential risks as listed in the risk management plan, in patients withmacular oedema following RVO or non-infectious posterior segment uveitis who aretreated with OZURDEX® under conditions of routine medical practice.

Study Design

Non-interventional study design
Cohort
Other

Non-interventional study design, other
Post-Authorization Safety Study, Prospective, observational study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
100000098436
dexamethasone

Additional medical condition(s)
Macular Oedema secondary to Central Retinal Vein Occlusion (CRVO) or Branch Retinal Vein Occlusion (BRVO) and inflammation of the posterior segment of the eye presenting as non-infectious uveitis (non-infectious posterior segment uveitis)

Population studied

Short description of the study population
Patients who are treated with OZURDEX for macular oedema following Branch retinal vein occlusion (BRVO) or Central retinal vein occlusion (CRVO), or non-infectious posterior segment uveitis, under conditions of routine medical practice in accordance with the SmPC.

Inclusion Criteria:
1. Age ? 18 years
2. Physician diagnosis of macular oedema following either Branch Retinal Vein Occlusion (BRVO) or Central Retinal Vein Occlusion (CRVO) or non-infectious posterior segment uveitis.
3. Treatment with OZURDEX (either initial or repeat)
4. Patients treated with OZURDEX in a completed clinical trial were eligible
5. Patient or legal representative provides informed consent according to local regulations

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
Macular oedema patients

Estimated number of subjects
650

Study design details

Outcomes
To evaluate the long-term safety of OZURDEX®, including the identified and potential risks as listed in the risk management plan, in patients with macular oedema following RVO or non-infectious posterior segment uveitis who are treated with OZURDEX® under conditions of routine medical practice.

Data analysis plan
All SAEs and ADRs of special interest will be recorded and coded using MedDRA terms and presented by SOC, HLT, and PT. The demographic and clinical profile of the study population will be described using baseline data. All analyses will be stratified by indication and by new initiators of OZURDEX versus previously treated with OZURDEX. Frequency of SAEs and ADRs of special interest will be calculated as the number of patients who have a specific event starting during the study period, divided by the number of patients enrolled, multiplied by 100. Incidence rates of SAEs and ADRs of special interest will be estimated by dividing the number of incident cases by the person-time at risk and as annualized rates. Time at risk will be defined as the time between dates of first injection of OZURDEX to end of follow-up (completion of follow-up / study discontinuation). Case narratives will be provided for each SAE and ADRs of special interest.

Documents

Study results
Allergan_Ozurdex_PASS_Abstract_Redacted.pdf(682.66 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
No