INJECT: Investigation of JETREA® in patients with confirmed vitreo-macular traction

First published: 22/08/2013

Last updated: 31/03/2024

Study | Finalised

Administrative details

EU PAS number

EUPAS4554

Study ID

23678

DARWIN EU® study

No

Study countries

- Canada
- Germany
- Netherlands
- Norway
- Portugal
- Spain

United Kingdom

Study description

The purpose of this study is to evaluate safety, clinical effectiveness, and health-related quality of life outcomes in a real world setting among a large population of patients exposed to ocriplasmin (JETREA®) across different countries according to each country's approved indications.

Study status

Finalised

Research institutions and networks

Institutions

Novartis Pharmaceuticals

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Claudio Spera ClinicalTrial.Disclosure@alcon.com

Study contact

ClinicalTrial.Disclosure@alcon.com

Primary lead investigator

Claudio Spera

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 12/06/2013

Study start date

Planned: 31/01/2014

Actual: 24/01/2014

Date of interim report, if expected

Planned: 31/07/2014

Actual: 09/10/2014

Date of final study report

Planned: 02/02/2017

Actual: 04/12/2017

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Alcon, A Novartis Division

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

M-13-046

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

Effectiveness study (incl. comparative)

Other

If ‘other’, further details on the scope of the study

Quality of Life

Data collection methods:

Primary data collection

Main study objective:

The purpose of this study is to evaluate safety, clinical effectiveness, and health-related quality of life outcomes in a real world setting among a large population of patients exposed to ocriplasmin (JETREA®) across different countries according to each country's approved indications.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Vitreomacular interface abnormal

Population studied

Short description of the study population

Patients exposed to ocriplasmin (JETREA®) across different countries according to each country's approved indications.

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 vitreomacular interface abnormality

Estimated number of subjects

3000

Study design details

Outcomes

Best-corrected visual acuity, pharmacological vitreo-macular traction resolution, pharmacological closure of macular hole, occurrence of vitrectomy, responses to NI VFQ-25 health-related quality of life questionnaire

Data analysis plan

Underlying baseline demographic and clinical characteristics of patients enrolled in the study will be summarised in tabular format. For continuous variables, descriptive statistics will include the number of non-missing

observations N, mean and standard deviation mean, (SD), median and interquartile range median, (Q1, Q3), minimum and maximum values min, max, and number of missing observations missing, N. For categorical variables, descriptive statistics will include the frequency and percentage (n,%) of non-missing values in each category.

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