Use of Intravitreal JETREA in Clinical Practice: A European Prospective Drug Utilisation Study (TG-MV-017) (TULIP)

First published: 21/10/2013

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Study Finalised

Administrative details

EU PAS number

EUPAS4796

Study ID

27262

DARWIN EU® study

No

Study countries

Germany

Italy

Spain

United Kingdom

Study description

This study is a European, multicentre, observational study. The study includes two parts, a drug utilisation study (DUS) and a Patient Educational Material Evaluation Survey (PEMES). The main objective of the DUS is to document JETREA® utilisation patterns in real-life clinical practice (including off label use and medication errors). The objective of the PEMES is to assess the effectiveness of the risk minimisation measures (i.e. the educational material provided to patients prior to the injection of JETREA®). The PEMES will be carried out in a subset of patients participating in the DUS.

Study status

Finalised

Research institutions and networks

Institutions

ThromboGenics NV

Multiple centres: 37 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Lore Gijsen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 07/11/2012

Actual: 07/11/2012

Study start date

Planned: 30/05/2014

Actual: 14/10/2014

Data analysis start date

Actual: 31/10/2017

Date of final study report

Planned: 14/10/2018

Actual: 22/02/2018

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?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The main objective of the DUS is to document JETREA® utilisation patterns in real-life clinical practice (including off label use and medication errors).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational study

Population studied

Short description of the study population

Patients with vitreomacular traction (VMT), on which ophthalmologists independently decided to administer Ocriplasmin (JETREA).

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- 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

300

Study design details

Data analysis plan

All data collected, including patient demographics, medical, general ocular and ocular intervention history, current ocular status, JETREA® utilisation information and anticipated treatment plan for the patient will be analysed descriptively.

Documents

Study results

TG-MV-017_EU-PAS_abstract.pdf (123.33 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