A prospective observational study conducted in France to describe routine clinical practice for treatment naïve or previously treated patients with diabetic macular edema (DME) who are starting IVT aflibercept (APOLLON)

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Study Finalised

Administrative details

EU PAS number

EUPAS15687

Study ID

37890

DARWIN EU® study

No

Study countries

France

Study description

The main objectives of this observational study are to describe outcomes, monitoring and treatment patterns of patients with diabetic macular edema in routine clinical practice who are either treatment naïve patients or previously treated patients. The total study population will be evaluated as well as the two subgroups (previously treated patients and treatment naïve patients). This study is designated to answer French Health Authority (HAS Haute Autorité de Santé) requirements.

Study status

Finalised

Research institutions and networks

Institutions

Multiple centres: 61 centres are involved in the study

Contact details

Study institution contact

Bayer Clinical Trials Contact Bayer AG clinical-trials-contact@bayer.com

Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Bayer Clinical Trials Contact Bayer AG

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 08/03/2016

Study start date

Planned: 30/06/2016

Actual: 21/09/2016

Date of final study report

Planned: 22/07/2020

Actual: 06/07/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

18636_Protocol_APOLLON_version 1.1_29Feb2016.pdf (1005.58 KB)

Protocol APOLLON_V2.0_13012017_Bayer.pdf (801.77 KB)

Regulatory

Was the study required by a regulatory body?

No

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

EU RMP category 3 (required)

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

Drug utilisation

Effectiveness study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The main objectives of this observational study are to describe effectiveness outcomes, monitoring and treatment patterns of in patients with DME in routine clinical practice who are either treatment naïve patients or previously treated patients. The total study population will be evaluated as well as the 2 subgroups (previously treated patients and treatment naïve patients).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(S01LA05) aflibercept

aflibercept

Medical condition to be studied

Diabetic retinopathy

Population studied

Short description of the study population

The study population will consist of patients with diabetic macular edema (DME) who have not been treated with aflibercept ever, and initiating treatment with IVT aflibercept per the ophthalmologist ‘s discretion. The prescription of the medicines is clearly separated from the decision to include the patient in the study. Patients population will be divided in two subgroups : Treatment naïve patient : Not previously treated with an anti-VEGF agent, macular laser photocoagulation (laser) or intravitreal steroid injection or implant (steroids) and initiating treatment with IVT aflibercept Previously treated patient : Already treated with any other treatment such as an anti-VEGF agent (other than IVT aflibercept), macular laser photocoagulation (laser), intravitreal steroid injection or implant (steroids) and initiating treatment with IVT aflibercept Female and male patients with a diagnosis of DME will be enrolled after the decision for treatment with IVT aflibercept has been made by the investigator. If patient receiving bilateral treatment, eye with the worst visual acuity at baseline will be considered as study eye.

Inclusion criteria

1. Male or female aged 18 years or older
2. Patient diagnosed with a visual impairment due to DME (as defined by HAS recommendation)
3. Patients in whom a decision to treat with IVT aflibercept has been made independently of the patient enrollment in the study
4. Patient diagnosed with type 1 or 2 diabetes mellitus
5. Patient who has been given appropriate information about the study and who has given his/her written, informed consent

Exclusion criteria

1. Patient with other retinal disease at the time of inclusion
2. Patients currently being treated with IVT aflibercept. This study will only include patients new to IVT aflibercept.

3. Systemic use of any anti / pro VEGF therapy

4. Patient taking part in an interventional study

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

Diabetic macular edema patients

Estimated number of subjects

400

Study design details

Outcomes

Mean change in Best Corrected Visual Acuity from baseline to month 12 in treatment naïve patients and previously treated patients, Mean change in Best Corrected Visual Acuity between baseline and 12-month follow-up for the entire study populationMean change in Best Corrected Visual Acuity between baseline and 24-month follow-up for all groupsMean change in Central Retinal Thickness between baseline and 12-month follow-up for all groups(More secondary outcomes is posted on www.ClinicalTrials.gov)

Data analysis plan

Statistical analyses will be explorative and descriptive only. All processes concerning patient validity, data consistency checks, permissible data modifications will be described in detail in the Data Management Plan. All statistical details including calculated variables and proposed format and content of tables will be detailed in the Statistical Analysis Plan.

Documents

Study results

18636_EU PAS Abstract_Redacted_Version 1.0_2020-07-06.pdf (633.48 KB)

Study report

18636_Clinical Study Report_Redacted_Version 1.0_2020-07-06.pdf (9.74 MB)

18636_Interim report_V1.0_2018-07-03.pdf (2.69 MB)

Study, other information

18636_Interim report_V1.0_2018-07-03.pdf (2.69 MB)

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

No