Incidence of Central Retinal Artery Occlusion in the Neovascular Age-related Macular Degeneration Population (RAO in neovascular AMD)

First published: 20/04/2020

Last updated: 13/03/2024

Study Finalised

Administrative details

EU PAS number

EUPAS34826

Study ID

48496

DARWIN EU® study

No

Study countries

United Kingdom

Study description

There is concern over increased risk of central Retinal Artery Occlusion (cRAO) following exposure to intravitreal aflibercept for which neovascular (wet) age-related macular degeneration (nAMD) is the principal indication. There is a marked paucity of published data describing the incidence of cRAO in the general population. A request has been made for additional data on the incidence of RAO in the nAMD population to support the regulatory decision-making process. The aims of this study are: (i) To establish the incidence of recorded cRAO in the general (IMRD-UK) population stratified by age, sex and smoking status, (ii) To compare the incidence of recorded cRAO rate between IMRD-UK and existing published studies, (iii) To describe the demographic makeup of the population with recorded nAMD in IMRD-UK by age, sex and smoking status, (iv) To derive an estimate of the incidence of recorded cRAO (and any RAO) standardised to the recorded nAMD population (stratified by both age & sex AND age, sex & smoking status), and, (v) To describe the actual incidence of recorded cRAO (and any RAO) in the nAMD population (accepting that numbers will be very low with both the underlying condition and outcome of interest being relatively rare).

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

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Study contact

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Primary lead investigator

Robert Flynn

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/04/2020

Actual: 01/04/2020

Study start date

Planned: 01/04/2020

Actual: 01/04/2020

Data analysis start date

Planned: 01/05/2020

Date of interim report, if expected

Planned: 31/05/2020

Date of final study report
Planned: 30/06/2020

Actual: 31/05/2020

Sources of funding

- Other

More details on funding

Internal funding

Study protocol

Protocol RAO in AMD.pdf (267.69 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Data collection methods:

Secondary use of data

Main study objective:

To establish the incidence of recorded central Retinal Artery Occlusion in the general (IMRD-UK) population stratified by age, sex and smoking status.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Retinal artery occlusion

Age-related macular degeneration

Additional medical condition(s)

Specifically neovascular age-related macular degeneration

Population studied

Short description of the study population

The study included age-related macular degeneration (nAMD) population assessed annually from 2000 to 2018 identified from the IMRD-UK (formerly known as THIN) database.

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 retinal artery occlusion and age-related macular degeneration

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Estimated number of subjects

5.000

Study design details

Outcomes

Central Retinal Artery Occlusion, Other Retinal Artery Occlusion

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Data analysis plan

Incidence rates will be calculated as the number of incident cases of RAO divided by the total population follow up time and is described as the event rate

per 100,000 person years (PY). This will be stratified by age category, sex and smoking status. To allow comparison with previous incidence studies, incidence rates will be applied to the 1976 European reference population. To establish the expected event rate in the nAMD population, event rates will be applied to the nAMD population stratified by age & sex, and age, sex & smoking status. Confidence intervals for all standardised incidence rates will be calculated using the approach of Greenland et al (Introduction to Stratified Analysis. In Modern Epidemiology). The actual rate of cRAO in the nAMD population will be calculated as the incidence number of cases divided by the patient years at risk during follow-up, although it is anticipated numbers will be low.

Documents

Study results

EMA report on Aflibercept - EYLEA - Retinal artery occlusion.pdf (513.55 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 source(s)

THIN® (The Health Improvement Network®)

Data sources (types)

Electronic healthcare records (EHR)

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