Cohort study to quantify the risk of glaucoma with intravitreal VEGF inhibitors (bevacizumab, ranibizumab, aflibercept)

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42994

EU PAS number

EUPAS42993

Study ID

42994

DARWIN EU® study

No

Study countries

☐ Canada

Italy

Study status

Planned

Research institutions and networks

Institutions

University of Siena

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of British Columbia

First published: 01/02/2024

Last updated: 01/02/2024

Institution

University of Pisa

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Institution

University of Firenze Firenze, Azienda Ospedaliera Universitaria Senese Siena, University of British Columbia Vancouver, University of Pisa Pisa

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Andrea Spini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/09/2020

Study start date

Planned: 15/09/2021

Date of final study report

Planned: 15/12/2021

Sources of funding

- Other

More details on funding

Regional funding (Tuscany region)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Main study objective:

What is the risk of glaucoma surgery among non-diabetic new users of anti-VEGF drugs for ocular diseases in Tuscany, Italy, compared across brands?

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XX44) aflibercept

aflibercept

(L01XC07) bevacizumab

bevacizumab

(S01LA04) ranibizumab

ranibizumab

Medical condition to be studied

Glaucoma

Population studied

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)

Estimated number of subjects

500

Study design details

Outcomes

risk of glaucoma surgery, risk of glaucoma diagnosis

Data analysis plan

Descriptive statistics: i.e number of users of bevacizumab, ranibizumab, aflibercept in the study population. Mean age by different drugs. Compute covariate distributions (age, gender by drug type). Average number of injection during follow-up for all three drugs. Crude number of outcomes (glaucoma surgeries and glaucoma outcome) by different exposure strata Cox regression to compute Hazard ratios: First, perform an intention to treat analysis i.e exposure is defined as index drug based on the first injection (‘Time on’) followed forward to an event (outcome 1 or 2) or censored based on above criteria. Adjustment: Age, use of oral corticosteroids, gender, comorbidities, binocularity.

Data management

Data sources

Data source(s)

ARS Toscana

Data source(s), other

ARS

Data sources (types)

Administrative healthcare records (e.g., claims)

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