Pattern of use of intravitreal drugs with antiangiogenic properties for age-related macular degeneration and other vascular retinopathies (Anti-VEGF drugs)

First published: 08/10/2016

Last updated: 29/03/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/16444

EU PAS number

EUPAS15749

Study ID

16444

DARWIN EU® study

No

Study countries

Italy

Study description

This is a drug utilization study of antiVEGF drugs for the treatment of age related macular degeneration and other vascular retinopathies in clinical practice, in the Tuscany region of Italy, from 2011 to 2015

Study status

Finalised

Research institutions and networks

Institutions

Agenzia regionale di sanità della Toscana (ARS)

Italy

First published: 01/02/2024

Last updated: 12/03/2024

Institution | **EU Institution/Body/Agency** | **ENCePP partner**

Contact details

Study institution contact

Rosa Gini

Study contact

rosa.gini@ars.toscana.it

Primary lead investigator

Rosa Gini

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 09/03/2016

Actual: 03/03/2016

Study start date

Planned: 05/09/2016

Actual: 05/09/2016

Data analysis start date

Planned: 12/09/2016

Actual: 12/09/2016

Date of final study report

Planned: 17/10/2016

Actual: 28/11/2016

Sources of funding

- Other

More details on funding

Self-funded by ARS

Study protocol

Pattern of use drugs for AMD treatment_to_publish.pdf(108.47 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

To describe the pattern of use of anti-VEGF drugs for the treatment of age-related macular degeneration and other vascular retinopathies in clinical practice in Tuscany, Italy

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Pharmacoepidemiological study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(L01XC07) bevacizumab

bevacizumab

(S01CB01) dexamethasone

dexamethasone

(S01LA03) pegaptanib

pegaptanib

(S01LA04) ranibizumab

ranibizumab

(S01LA05) aflibercept

aflibercept

Medical condition to be studied

Diabetic retinopathy

Diabetic retinal oedema

Age-related macular degeneration

Population studied

Short description of the study population

Patients with diabetic retinopathy, retinal oedema or age-related macular degeneration in the Tuscany region of Italy, from 2011 to 2015.

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 diabetic retinopathy, retinal oedema or age-related macular degeneration

Estimated number of subjects

15000

Study design details

Outcomes

Number of injections per year and intra-injections interval, switchingless than 5 injections in the first year

Data analysis plan

Outcomes will be compared across incident users of the drugs. Subgroup analysis will be performed in patients with a sufficient number of contacts with ophthalmic services (interval between consecutive contacts not longer than 3 months) and in patient with at least 3 injections

Documents

Study results

report_antiVEGF.pdf(213.74 KB)

Study publications

Farmaco-utilizzazione di farmaci per il trattamento della degenerazione macular...

Data management

Data sources

Data source(s)

ARS Toscana

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

Data sources (types), other

Disease-specific exemptions from copayment

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