

# 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

### Contact details

#### Study institution contact

Rosa Gini

Study contact

[rosa.gini@ars.toscana.it](mailto:rosa.gini@ars.toscana.it)

#### Primary lead investigator

Rosa Gini

Primary lead investigator

#### 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 institution 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

## Study timelines

### Date when funding contract was signed

Planned:

09/03/2016

Actual:

03/03/2016

---

### Data collection

Planned:

05/09/2016

Actual:

05/09/2016

---

### **Start date of data analysis**

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 data collection

---

**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**

100000096721

bevacizumab

100000098481

dexamethasone

100000098600

pegaptanib

100000098601

ranibizumab

100000135940

aflibercept

---

**Medical condition to be studied**

Diabetic retinopathy

Diabetic retinal oedema

## 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, switching less 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

### Results tables

[report\\_antiVEGF.pdf](#)(213.74 KB)

---

### Study publications

## Data management

### Data sources

**Data source(s)**

ARS Toscana

---

**Data sources (types)**

[Administrative data \(e.g. claims\)](#)

[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