

# 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

### EU PAS number

EUPAS15749

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### Study ID

16444

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### DARWIN EU® study

No

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### Study countries

 Italy

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### 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

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## Study status

Finalised

## Research institutions and networks

### Institutions

[Agenzia regionale di sanità della Toscana \(ARS Toscana\)](#)

 Italy

**First published:** 01/02/2024

**Last updated:** 23/03/2026

**Institution**

**EU Institution/Body/Agency**

**ENCePP partner**

## Contact details

### Study institution contact

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**Study contact**

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

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### **Study start date**

Planned: 05/09/2016

Actual: 05/09/2016

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### **Data analysis start date**

Planned: 12/09/2016

Actual: 12/09/2016

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### **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

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**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

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**Study type:**

Non-interventional study

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**Scope of the study:**

Drug utilisation

**Data collection methods:**

Secondary use of data

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**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

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**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

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### **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.

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### **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)
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### **Special population of interest**

Other

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### **Special population of interest, other**

Patients with diabetic retinopathy, retinal oedema or age-related macular degeneration

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### **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

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## 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)

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### Study publications

[Farmaco-utilizzazione di farmaci per il trattamento della degenerazione macular...](#)

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## 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)**

ARS Toscana

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**Data sources (types)**

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Other

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**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

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**Check completeness**

Unknown

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**Check stability**

Unknown

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**Check logical consistency**

Unknown

## Data characterisation

## **Data characterisation conducted**

Unknown