Real-life data study of the French cohort of patients with Rendu Osler disease treatment with bevacizumab:the CoBevaRO study.

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/1000000548

EU PAS number

EUPAS1000000548

Study ID

1000000548

DARWIN EU® study

No

Study countries

France

Study description

This real-world data (RWD) study aims to generate real-world evidence (RWE) on the effectiveness and safety of systemic bevacizumab in the management of bleeding and cardiac manifestations in patients with hereditary hemorrhagic telangiectasia (HHT, also known as Rendu-Osler disease).

The analysis is based on data extracted from the French CIROCO database on October 23, 2024, and focuses on patients with a documented history of bevacizumab treatment between 2009 and 2023.

The study objectives are to characterise real-life prescription practices, including dosing, frequency, and treatment duration;

to assess the safety profile through reported adverse events;

to evaluate clinical effectiveness using parameters such as haemoglobin levels, red blood cell transfusion requirements, iron supplementation, and cardiac index;

to compare the use of originator bevacizumab (AVASTIN®) versus biosimilars; and to explore differential outcomes across patient subgroups based on age, genetic mutation, and location of arteriovenous malformations.

The ultimate goal is to support optimised therapeutic strategies and inform clinical decision-making in the treatment of HHT-related bleeding.

Study status

Ongoing

Research institutions and networks

Institutions

Hospices Civils de Lyon (HCL)

France

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Institution | Educational Institution | Healthcare Professional Organisation/Association/Learning Society | Hospital/Clinic/Other health care facility

INSERM

France

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Institution | Other

Networks

OrphanDev

Contact details

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Study timelines

Date when funding contract was signed

Actual: 26/09/2024

Study start date

Actual: 23/10/2024

Data analysis start date

Actual: 24/10/2024

Date of final study report

Planned: 30/06/2025

Sources of funding

- Non-EU institutional research programme
- Pharmaceutical company and other private sector

More details on funding

This study is funded by both the French National Research Agency (ANR) and Delbert Pharma.

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

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

Data collection methods:

Secondary use of data

Study Design

Non-interventional study design

Case-only

Cohort

Study drug and medical condition

Name of medicine

AVASTIN

MVASI

ZIRABEV

ABEVMY

AYBINTIO

VEGZELMA

ALYMSYS

Study drug International non-proprietary name (INN) or common name

BEVACIZUMAB

Anatomical Therapeutic Chemical (ATC) code

(L01FG01) bevacizumab

bevacizumab

Medical condition to be studied

Hereditary haemorrhagic telangiectasia

Population studied

Short description of the study population

The study population consists of a subset of patients from the CIROCO database who meet specific inclusion criteria.
All included individuals are adults aged 18 years or older, diagnosed with hereditary hemorrhagic telangiectasia (HHT, or Rendu-Osler disease), and have received systemic bevacizumab exclusively as part of routine clinical care for HHT-related manifestations.
Patients treated with bevacizumab for oncological indications or those who received the drug solely within the framework of a clinical trial were excluded from the data extraction and therefore from the analysis.
Only patients followed and treated in France were considered, and all individuals included in the study have not objected to the use of their anonymised health data in accordance with applicable data protection regulations.

Age groups

Adult and elderly population (≥18 years)

Adults (18 to < 65 years)

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Elderly (≥ 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

237

Data management

Data sources

Data source(s)

Clinical Investigation and research for the Rendu Osler Cohort

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Data sources (types)

Disease registry

Drug prescriptions

Non-interventional study

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