

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

**First published:** 11/04/2025

**Last updated:** 06/05/2025

Study

Ongoing

## Administrative details

### EU PAS number

EUPAS1000000548

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### Study ID

1000000548

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### DARWIN EU® study

No

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### Study countries

 France

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### 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.

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## Study status

Ongoing

## Research institutions and networks

### Institutions

Hospices Civils de Lyon (HCL)

 France

**First published:** 09/04/2025

**Last updated:** 24/07/2025

**Institution**

Educational Institution

Hospital/Clinic/Other health care facility

**INSERM**

 France

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

**Last updated:** 01/02/2024

**Institution**

Other

## Networks

**OrphanDev**

## Contact details

### **Study institution contact**

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**Study contact**

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### **Primary lead investigator**

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Primary lead investigator

**ORCID number:**

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## Study timelines

**Date when funding contract was signed**

Actual: 26/09/2024

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**Study start date**

Actual: 23/10/2024

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**Data analysis start date**

Actual: 24/10/2024

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**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

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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

Effectiveness study (incl. comparative)

Safety study (incl. comparative)

**Data collection methods:**

Secondary use of data

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**Study Design**

## **Non-interventional study design**

Case-only

Cohort

## Study drug and medical condition

### **Medicinal product name**

AVASTIN

MVASI

ZIRABEV

ABEVMY

AYBINTIO

VEGZELMA

ALYMSYS

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

BEVACIZUMAB

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### **Anatomical Therapeutic Chemical (ATC) code**

(L01FG01) bevacizumab

bevacizumab

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### **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.

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## **Age groups**

- **Adult and elderly population ( $\geq 18$  years)**

- Adults (18 to < 65 years)
    - Adults (18 to < 46 years)
    - Adults (46 to < 65 years)
  - Elderly ( $\geq 65$  years)
    - Adults (65 to < 75 years)
    - Adults (75 to < 85 years)
    - Adults (85 years and over)
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## **Estimated number of subjects**

237

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)

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

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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**

No