

# Meningioma medroxyprogesterone feasibility assessment in the IDA Germany and IMRD UK databases

**First published:** 03/10/2025

**Last updated:** 03/10/2025

Study

Finalised

## Administrative details

### EU PAS number

EUPAS1000000493

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### Study ID

1000000493

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### DARWIN EU® study

No

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### Study countries

 Germany

 United Kingdom

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### Study description

A descriptive study to measure exposure to medroxyprogesterone in women, and the number of women meningioma who have been prescribed medroxyprogesterone. These descriptive data will be used to inform decision making around the feasibility of a larger network study.

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### **Study status**

Finalised

## Research institutions and networks

### Institutions

#### European Medicines Agency (EMA)

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

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**Institution**

## Contact details

### **Study institution contact**

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**Study contact**

[daniel.morales@ema.europa.eu](mailto:daniel.morales@ema.europa.eu)

### **Primary lead investigator**

Daniel Morales

Primary lead investigator

## Study timelines

### **Date when funding contract was signed**

Planned: 28/10/2024

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### **Study start date**

Planned: 28/10/2024

Actual: 28/10/2024

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### **Data analysis start date**

Planned: 28/10/2024

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### **Date of final study report**

Planned: 13/11/2024

Actual: 13/11/2024

## Study protocol

[Study Protocol Meningioma medroxyprogesterone feasibility.pdf](#) (210.92 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 topic:**

Disease /health condition

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**Study type:**

Non-interventional study

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**Scope of the study:**

Feasibility analysis

**Study design:**

Descriptive cohort study

**Main study objective:**

To described medroxyprogesterone in women according to dose and age and prior history of meningioma.

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Progesterone

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**Medical condition to be studied**

Meningioma

## Population studied

## Short description of the study population

General female population

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### Age groups

- **Paediatric Population (< 18 years)**
  - Infants and toddlers (28 days - 23 months)
  - Children (2 to < 12 years)
  - Adolescents (12 to < 18 years)
- **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)

## Study design details

### Setting

Primary care electronic health records

## Documents

### Study report

[Study Report Meningioma medroxyprogesterone feasibility.pdf](#) (668.03 KB)

## 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)

IQVIA Disease Analyzer Germany

IQVIA Medical Research Data - OMOP

## Use of a Common Data Model (CDM)

### CDM mapping

No

## Data quality specifications

### Check conformance

Yes

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### Check completeness

Yes

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### Check stability

Yes

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### Check logical consistency

Yes

## Data characterisation

**Data characterisation conducted**

Not applicable