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

First published: 03/10/2025

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Study Finalised

Administrative details

EU PAS number

EUPAS1000000493

Study ID

1000000493

DARWIN EU® study

No

Study countries

Germany

United Kingdom

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.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Daniel Morales

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 28/10/2024

Study start date
Planned: 28/10/2024

Actual: 28/10/2024

Data analysis start date
Planned: 28/10/2024

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

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study topic:

Disease /health condition

Study type:

Non-interventional study

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

Medical condition to be studied

Meningioma

Population studied

Short description of the study population

General female population

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

Check completeness

Yes

Check stability

Yes

Check logical consistency

Yes

Data characterisation

Data characterisation conducted

Not applicable