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

First published: 03/10/2025

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Administrative details

Study description

EU PAS number		
EUPAS1000000493		
Study ID		
1000000493		
DARWIN EU® study		
No		
Study countries		
Germany		
United Kingdom		

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)

First published: 01/02/2024

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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

Name of medicine, 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