Cyproterone-containing medicines and Meningiomas - An EudraVigilance analysis

First published: 21/01/2021

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS39144

Study ID

39145

DARWIN EU® study

No

Study countries

☐ Netherlands

Study description

This was a descriptive study of meningiomas reported to cyproterone-containing medicines using EudraVigilance data.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Pinheiro Luis

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 01/08/2019

Actual: 01/08/2019

Study start date
Planned: 01/08/2019

Actual: 01/08/2019

Data analysis start date
Planned: 01/08/2019

Actual: 01/08/2019

Date of interim report, if expected
Planned: 02/09/2019

Actual: 26/09/2019

Date of final study report
Planned: 12/09/2019

Actual: 04/10/2019

Sources of funding

- EMA

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

Methodological aspects

Study type

Study topic:

Human medicinal product

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Other

If ‘other’, further details on the scope of the study

Case series review of Pharmacovigilance data

Data collection methods:

Secondary use of data

Main study objective:

The primary objective of the EudraVigilance analysis was to identify and describe case reports to cyproterone-containing medicinal products and to identify and characterise case reports to these products where meningiomas were also reported.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Case-series

Study drug and medical condition

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

CYPROTERONE

CYPROTERONE ACETATE

Medical condition to be studied

Meningioma malignant

Meningioma benign

Population studied

Short description of the study population

Case reports of meningioma cases to cyproterone -containing medicinal products in EudraVigilance database.

Age groups

- Preterm newborn infants (0 – 27 days)
- Term newborn infants (0 – 27 days)
- Infants and toddlers (28 days – 23 months)
- Children (2 to < 12 years)
- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)
- Adults (65 to < 75 years)
- Adults (75 to < 85 years)
- Adults (85 years and over)

Estimated number of subjects

871

Study design details

Data analysis plan

Descriptive statistics were performed by age, gender, indication for use, route of administration and origin of reports for all case reports. Where feasible, boxplots of age and time to onset were plotted.

Documents

Study results

Cyproterone and meningiomas - EV report - v.2.1- 20191004.pdf (1.31 MB)

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), other

EudraVigilance

Data sources (types)

Spontaneous reports of suspected adverse drug reactions

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