Post Authorization Safety Study: Knowledge about safety precautions among physicians in Denmark prescribing CPA/EE products

First published: 02/11/2015

Last updated: 11/08/2016

Study Finalised

Administrative details

EU PAS number

EUPAS11414

Study ID

14684

DARWIN EU® study

No

Study countries

☐ Denmark

Study description

The study first included a DUS study. Objective: Indications for prescribing CPA/EE products among physicians in Denmark. To collect information about the indications physicians use for prescribing CPA/EE products in current clinical practice in Denmark.PASS objective: To collect information about physicians' knowledge of contraindications and the key safety precautions to be observed when prescribing CPA/EE products in current clinical practice in Denmark.

Study status

Finalised

Research institutions and networks

Institutions

Orifarm Generics

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Contact details

Study institution contact

Dorte Jensen pharmacovigilance@orifarm.com

Study contact

pharmacovigilance@orifarm.com

Primary lead investigator

Dorte Jensen

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 24/10/2014

Actual: 24/10/2014

Study start date

Planned: 01/03/2015

Actual: 02/03/2015

Date of final study report

Planned: 01/05/2015

Actual: 20/04/2015

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Orifarm Generics A/S

Study protocol

141208DUS_PASS protocols.pdf(238.63 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

DUS: To collect information about the indications physicians use for prescribing CPA/EE products in current clinical practice in Denmark.PASS: To collect

information about physicians’ knowledge of contraindications and the key safety precautions to be observed when prescribing CPA/EE products in current clinical practice in Denmark.

Study Design

Non-interventional study design

Cross-sectional

Other

Non-interventional study design, other

Post Authorisation Safety Study

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03HB01) cyproterone and estrogen

cyproterone and estrogen

Population studied

Short description of the study population

Physicians in Denmark prescribing cyproterone and estrogen products.

Age groups

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

0

Study design details

Outcomes

Does physicians use the correct indications for prescribing CPA/EE products in current clinical practice in Denmark.Are physicians’ knowledge of contraindications and key safety precautions correct, when prescribing CPA/EE products in current clinical practice in Denmark.

Data analysis plan

Each questionnaire will be reviewed for completeness and for possible errors prior to data entry. A detailed review and analysis of responses to individual questions with summaries across logical groupings of response items will be made. Results will be stratified by logical variables, if relevant and possible. Descriptive statistics will be used to indicate how many percent of the doctors that gave correct replies to the yes or no questions (nominal scale). Confidence intervals will be calculated to describe the variation in the likely true value in the population of regular prescribers. Accounting for non-participants will be also be performed. Information in the report will be anonymous with regard to source.

Documents

Study results

150512DUS_PASS report_final.pdf(195.25 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Physicians (General practicioners)

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