Drug Utilization Study on the Prescribing Indications for CPA/EE in 5 European Countries

First published: 20/01/2015

Last updated: 02/07/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/30829

EU PAS number

EUPAS8365

Study ID

30829

DARWIN EU® study

No

Study countries

☐ Austria

- [ ] Czechia
- [ ] France
- [ ] Netherlands
- [ ] Spain

Study description

Cyproterone acetate (CPA) 2mg, in combination with ethinylestradiol (EE) 35mcg is a medicinal product currently indicated for the treatment of moderate to severe acne in women of reproductive age. Due to the combination with EE and the dosing, the preparations also act as effective contraceptives. This multi-national, cross-sectional drug utilization study is designed to collect the reasons and specific indications for the prescription of CPA/EE. The primary objective of the study is to characterize the prescribing behaviors for CPA/EE in 5 European countries (Austria, Czech Republic, France, the Netherlands, and Spain), which includes the characterization of prescribing indications for CPA/EE, the use of CPA/EE in accordance with the updated label, concomitant use of CPA/EE and combined hormonal contraceptives (CHCs), and second line treatment of CPA/EE in the indication acne. As sample of 50 physicians per country will be asked to enroll a total of 5,000 study participants. Data will be captured via paper-based questionnaires that will be filled out by the participating physicians based on the patient’s statements and medical record information.

Study status

Finalised

Research institutions and networks

Institutions

Berlin Center for Epidemiology & Health Research, ZEG Berlin

Germany

First published: 06/08/2019

Last updated: 20/06/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Contact details

Study institution contact

Karl Pauls

Study contact

kpauls@zeg-berlin.de

Primary lead investigator

Klaas Heinemann

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 18/12/2013

Study start date

Planned: 01/02/2015

Actual: 10/03/2015

Date of final study report

Planned: 31/05/2016

Actual: 31/05/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer Pharma AG

Study protocol

Drug Utilization Study CPA_Study Protocol_FINAL.pdf(549.12 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Methodological aspects

Study type

Study type list

Study topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

The primary objective of the study is to characterize the prescribing behaviors for CPA/EE in 5 European countries, which includes the characterization of 1) prescribing indications for CPA/EE, 2) the use of CPA/EE in accordance with the updated label, 3) concomitant use of CPA/EE and combined hormonal contraceptives (CHCs), and 4) second line treatment of CPA/EE in the indication acne

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03HB01) cyproterone and estrogen

cyproterone and estrogen

Medical condition to be studied

Acne

Population studied

Short description of the study population

Women who receives a Cyproterone acetate (CPA)/ethinylestradiol (EE) prescription during the study period.

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

5000

Study design details

Outcomes

Proportion of off-label use per 100 prescriptions

Data analysis plan

The study focuses on point estimates and 95% confidence intervals for the percentage of off-label use of CPA/EE. Reasons for prescription of CPA/EE will be investigated with respect to concomitant hormonal contraceptive use and androgen-sensitive diseases. Data analysis will be stratified by country and by specialization of the prescribing physician. Intra cluster (physician level) correlation of subjects will be considered by adjusting confidence limits. The precision of the point estimates will be high enough to assess the extent of off-label use of CPA/EE in the respective countries. Pattern of prescription behavior and disease characteristics will be described. A detailed statistical analysis plan will be developed by the investigator before study start. This plan will include methodological details and a set of mock tables for the presentation of results. Analyses of this cross sectional study will be limited to descriptive data.

Documents

Study results

Final Report 2016_05_23_final.pdf(2.11 MB)

France Addendum (only France) 12_21vf.pdf(567.37 KB)

Study report

EU-PAS_Abstract_Template_DUS_CPA_EE (003).pdf(666 KB)

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Questionnaires will be filled out by the participating physicians (after the patient signed the informed consent) based on the woman’s statements and medical record information. This includes the use of hormonal contraceptive, reason for prescription, concomitant use of hormonal contraceptive and status of androgen-sensitive diseases will be documented by the prescribing physician.

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

Unknown