Drug utilization study of cyproterone/ethinylestradiol (Diane®-35 and generics) in the Netherlands, UK and Italy

First published: 23/01/2015
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/31117

EU PAS number
EUPAS8412

Study ID
31117

DARWIN EU® study
No

Study countries
Italy
Netherlands
Spain

Study description
The study objectives are to characterize new users of Cyproterone Acetate / Ethinylestradiol (CPA/EE) in 2011/2012 and in 2014 according to demographics, treatment characteristics, previous diagnosis of acne, hirsutism or other hyperandrogenic conditions, previous acne treatment and (concomitant) use of hormonal contraceptives identified in Healthcare Databases in the UK (THIN), the Netherlands (PHARMO) and Italy (HSD).

Study status
Finalised

Research institution and networks

Institutions

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands
First published: 07/01/2022
Last updated
10/01/2022

Institution
Laboratory/Research/Testing facility
ENCePP partner

Fundación Centro Español de Investigación Farmacoepidemiológica (CEIFE)

Spain
First published: 15/03/2010
Last updated
15/02/2024

Institution
Not-for-profit
ENCePP partner

Italy HIS: The Health Search institute

Networks

PHARMO: Database Network Netherlands

Contact details

Study institution contact

CTP Team / Ref: "ENCePP"/ Bayer Pharma AG Bayer HealthCare AG
Study contact

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Primary lead investigator
CTP Team / Ref: "ENCePP"/ Bayer Pharma AG Bayer HealthCare AG
Primary lead investigator

Study timelines

Date when funding contract was signed
Actual:
01/12/2014

Study start date
Planned:
01/02/2015
Actual:
01/05/2015

Date of final study report
Planned:
30/01/2016
Actual:
31/03/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer

Study protocol

17660_Study Protocol DUS Diane_2014-09-12.pdf(523.32 KB)

17660_02_Protocol_V7.0_2017_extension study.pdf(3.21 MB)

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:
Human medicinal product

Study type:
Non-interventional study

Scope of the study:
Drug utilisation

Data collection methods:
Secondary data collection

Main study objective:
Characterization of new users of Cyproterone Acetate / Ethinylestradiol CPA/EE in 2011/2012 and in 2014 according to demographics, treatment characteristics, previous diagnosis of acne, hirsutism or other hyperandrogenic conditions, previous acne treatment and (concomitant) use of hormonal contraceptives identified in Healthcare Databases in the UK (THIN), the NL (PHARMO) and Italy (HSD).

Study Design

Non-interventional study design
Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code
(G03HB) Antiandrogens and estrogens

Population studied

Short description of the study population
New Cyproterone Acetate / Ethinylestradiol (CPA/EE) users in 2011 and 2012.

Age groups
Adults (18 to < 46 years)
Adults (46 to < 65 years)

Estimated number of subjects
10000

Study design details

Outcomes
1. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of Acne2. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of Hirsutism3. Proportion (%) of new users of Diane-35 (or generics) with a previous diagnosis of other Hyperandrogenic Conditions (e.g. androgenic alopecia, seborrhea, polycystic ovary syndrome), 1. Determination of previous acne treatments (prescription drugs only) of Diane-35 (or generics) users with a previous diagnosis of acne.2. Proportion (%) of new Diane-35 (or generics) users, who have concomitant prescriptions of other combined oral contraceptives

Data analysis plan
Patient, treatment and diagnosis characteristics will be reported descriptively. Categorical data will be presented as counts (n) and proportions (%). Continuous data will be presented as means with standard deviation (SD) and as medians with inter quartile range (IQR) when appropriate. Results will be presented for the 2011/2012 users together and stratified by year of diagnosis.

Documents

Study results
17660_EU-PAS_Abstract.pdf(59.26 KB)
17660_Study Report DUS Diane - final.pdf(727.15 KB)

Study report
17660_04_Report.pdf(2.12 MB)
17660_04_Report extension.pdf(4.03 MB)
17660_04_Report_ 1_interim.pdf(727.05 KB)

Study, other information
17660_04_Report.pdf(2.12 MB)
17660_04_Report_ 1_interim.pdf(727.05 KB)

Data management

Data sources

Data source(s)
THIN® (The Health Improvement Network®)
PHARMO Data Network

Data source(s), other
HSD Italy

Data sources (types)
Administrative data (e.g. claims)
Drug dispensing/prescription data
Electronic healthcare records (EHR)

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