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

**First published:** 23/01/2015
**Last updated:** 23/04/2024

Study | Finalised

## Administrative details

### 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

**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 | ENCePP partner | Laboratory/Research/Testing facility

### 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

# Study timelines

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

**Data collection**
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 contracep

## Study Design

**Non-interventional study design**
Cohort

# Study drug and medical condition

**Anatomical Therapeutic Chemical (ATC) code**
100000095914
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

**Results tables**
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