Study to Evaluate Physician Knowledge of Safety and Safe Use Information for Diane-35 and Its Generics in Europe: An Observational Post-Authorisation Safety Study

First published: 07/04/2015

Last updated: 16/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS9312

Study ID

28239

DARWIN EU® study

No

Study countries

- ☐ Austria
- ☐ Czechia

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

Study status

Finalised

Research institutions and networks

Institutions

RTI Health Solutions (RTI-HS)

- [ ] France
- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom
- [ ] United Kingdom (Northern Ireland)
- [ ] United States

First published: 21/04/2010

Last updated: 13/03/2025

Institution | Not-for-profit | ENCePP partner

Multiple centres: 5 centres are involved in the study

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Elizabeth Andrews

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 18/08/2014

Actual: 18/08/2014

Study start date

Planned: 25/05/2015

Actual: 26/06/2015

Date of final study report

Planned: 30/06/2016

Actual: 15/08/2016

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer Pharm

Study protocol

Diane-35 protocol 20 April 2015.pdf (473.49 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:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this study is to measure physician knowledge and understanding of the key information contained in the Diane-35 educational material: Patient information card, and Prescribers' Checklist

Study Design

Non-interventional study design

Cross-sectional

Study drug and medical condition

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

CYPROTERONE ACETATE

Medical condition to be studied

Acne

Population studied

Short description of the study population

Physicians who have experience with Diane-35 or its generic versions in five European countries: Austria, the Czech Republic, the Netherlands, Spain, and France.

Physicians who met all of the following eligibility criteria were included:

1. Licensed and practicing dermatologist, gynaecologist, or general practitioner
2. Prescribed Diane-35 or a generic version to at least one patient in the past 6 months

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Age groups

- 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

759

Study design details

Outcomes

The knowledge of the physician concerning Diane-35

Data analysis plan

Analyses will include detailed review of responses to individual questions and potential summary measures across logical groupings of response items. Results will be stratified by country and other logical variables, such as physician specialty and experience with Diane-35 or its generics. A detailed

analysis plan describing methods of analysis and presentation and including table shells will be developed prior to starting data collection

Documents

Study results

17195_EU-PAS_Abstract.pdf (86.29 KB)

Study report

17195_Study Report_R-11092_final.pdf (3.41 MB)

Study, other information

17195_Diane-35_Manuscript.pdf (1.56 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 sources (types)

Other

Data sources (types), other

Cross-sectional data collection via a web-based questionnaire or a telephone interview

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