Patterns and Determinants of Use of Oral Contraceptives in the European Union (Use of OC in the EU)

First published: 17/08/2012

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/20752

EU PAS number

EUPAS2738

Study ID

20752

DARWIN EU® study

No

Study countries

☐ Italy

☐ Netherlands

☐ United Kingdom

Study description

The study aims to set the basis for future safety evaluations of oral contraceptive use in Europe, by assessing current user and treatment characteristics in daily practice in five European databases from the Netherlands, UK and Italy, capturing a source population of 25 million individuals. Specific study objectives are to assess among women using oral contraceptive in 2009 and 2010 in different countries in Europe: prevalence and incidence estimates, demographics, health indicators and morbidity and OC treatment characteristics.

Study status

Finalised

Research institutions and networks

Institutions

Erasmus Medical Centre Rotterdam

First published: 01/02/2024

Last updated: 01/02/2024

Institution

The PHARMO Institute for Drug Outcomes Research (PHARMO Institute)

Netherlands

First published: 07/01/2022

Last updated: 24/07/2024

Institution | Laboratory/Research/Testing facility | ENCePP partner

Synapse Research Management Partners, S.L. Barcelona, Spain, Agenzia regionale di sanità della Toscana Firenze, Italy, Università degli Studi di Milano-Bicocca Milano, Italy, EMC Rotterdam, Dept of Medical Informatics Rotterdam, the Netherlands

Networks

EU-ADR Alliance

First published: 01/02/2024

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Network

Contact details

Study institution contact

Katia Verhamme

Study contact

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Primary lead investigator

Miriam Sturkenboom

Primary lead investigator

Study timelines

Date when funding contract was signed

Actual: 02/12/2011

Study start date

Planned: 22/08/2012

Actual: 20/08/2012

Data analysis start date

Planned: 22/08/2012

Actual: 20/08/2012

Date of interim report, if expected

Planned: 25/10/2012

Actual: 25/10/2012

Date of final study report

Planned: 02/01/2013

Actual: 17/01/2013

Sources of funding

- EMA

Study protocol

D1.b_Final Study Protocol_v1.0 (OC).pdf(1.07 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

Not applicable

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 use of data

Main study objective:

Specific study objectives are to assess among women using oral contraceptive in 2009 and 2010 in different countries in Europe:- prevalence estimates (users on January 1, 2010)- incidence estimates (new users per year)- demographics- health indicators and morbidity- treatment characteristics

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03AA) Progestogens and estrogens, fixed combinations

Progestogens and estrogens, fixed combinations

(G03AB) Progestogens and estrogens, sequential preparations

Progestogens and estrogens, sequential preparations

(G03AC) Progestogens

Progestogens

Population studied

Short description of the study population

All women in the database any time in 2009 or 2010, and who have at least one year follow-up in the database.
All women with a prescription (IPCI, THIN) or dispensing (PHARMO, SISR-T, SISR-L) of oral contraceptives during study follow-up were selected as users.

Age groups

Children (2 to < 12 years)

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

1500000

Study design details

Data analysis plan

Descriptive statistics will include proportions, mean and standard deviations (sd), median and interquartile ranges (IQR) of the aggregated datasets. Incidence and prevalence will be presented for the pooled dataset as well as for the individual datasets. Population and treatment characteristics will be presented for the individual datasets. Stratified analysis will be performed per

database and separately for incident and prevalent users. In addition, analysis will be performed by age category and presented in strata if needed.

Documents

Study results

EMA OC. Del 2.b_Final.pdf(1.5 MB)

Study, other information

Note on data collection timelines.pdf(170.97 KB)

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

2012-0012-DoI-SDPP-2738.pdf(821.1 KB)

ENCePPDoIForm_EMCKV.pdf(269.92 KB)

Composition of steering group and observers

Participants in OC.pdf(260.6 KB)

Signed code of conduct

2012-0012-DoC CoC-SDPP-2738.pdf(42.2 KB)

Signed code of conduct checklist

2012-0012-Checklist CoC-SDPP-2738.pdf(497.3 KB)

Signed checklist for study protocols

2012-0012-Checklist Protocol-SDPP-2738.pdf(265.46 KB)

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

Integrated Primary Care Information (IPCI)

Data source(s), other

THIN, IPCI

Data sources (types)

Administrative healthcare records (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

Unknown