Study of utilisation of combined hormonal contraceptives in Europe

First published: 22/10/2017

Last updated: 02/07/2024

Study Finalised

Administrative details

EU PAS number

EUPAS21352

Study ID

40853

DARWIN EU® study

No

Study countries

Denmark

Netherlands

United Kingdom

Study description

This study has the following objectives1. To investigate trends in new user (initiators) prescribingpatterns in the two years preceding the relevantCommission Decision (January 2012 – January 2014)and in a similar period following the decision (February2014– December 2015).2. To investigate switching patterns between productsamong prevalent users including reasons for changes(e.g., reimbursement or regulatory and clinicalguidance).3. Within Objectives 1 and 2, to examine any changes inutilisation in groups defined by patient’s clinical anddemographic risk factors for VTE as detailed in thewarnings and contraindications in the European UnionSummary of Product Characteristics (SmPC).4. To examine any differences in the incidence rates of VTEbetween the two periods specified and, in light of theresults for Objective 1-3, to investigate any measurableassociation between the observed changes in CHC useand changes in the VTE incidence rates.

Study status

Finalised

Research institutions and networks

Institutions

Aarhus University & Aarhus University Hospital CLINICAL EPIDEMIOLOGY AND DATA SCIENCE, DEPARTMENT OF CLINICAL MEDICINE

Denmark

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Institution | Educational Institution

University College London Leiden University, the Netherlands

Networks

Aarhus University Consortium (ad-hoc)

Contact details

Study institution contact

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Primary lead investigator

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Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 23/11/2016

Actual: 23/11/2016

Study start date

Planned: 30/11/2017

Actual: 30/11/2017

Date of interim report, if expected

Planned: 01/08/2018

Actual: 01/08/2018

Date of final study report

Planned: 14/11/2018

Actual: 03/12/2018

Sources of funding

- EMA

Study protocol

Study of utilisation of combined hormonal contraceptives in Europe.pdf (393.15 KB)

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:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

1. To investigate trends in new user (initiators) prescribing patterns in the two years preceding the relevant Commission Decision 2. To investigate switching patterns between products among prevalent users3. To examine changes in users' clinical characteristics4. To examine differences in VTE einidence rates

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(G03F) PROGESTOGENS AND ESTROGENS IN COMBINATION

PROGESTOGENS AND ESTROGENS IN COMBINATION

Population studied

Short description of the study population

For the Dutch drug utilization study and cohort study: All women between the ages of 18-49 years with at least one prescription of combined oral contraceptive use in the period from January 2012 through December 2015 will be included, i.e., both new users as well as prevalent users.
For the Danish drug utilization and cohort study: Women between the ages 18-49 years in the period January 2012- December 2015 will be included, i.e. both new and prevalent users.
For the UK drug utilization and cohort study: women between the ages 18-49 years who have been registered for at least two years prior with one of the general practices that contributed data to The Health Improvement Network (THIN) primary care database will be included.

Age groups

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

500.000

Study design details

Data analysis plan

For each calendar year, we provide - estimates of the number and proportion of new users of each oral contraceptive type and the number and proportion of switchers (from one type to another or to a different dose) - estimates of the proportion of each oral contraceptive type and the number of switchers (from one type to another or to a different pill strength) December 2015), we will perform segmented regression analysis.- number of initiators of each oral contraceptive type and the number of switchers (from one type to another or to a different dose) overall and stratified by age at initiation of CHC, social deprivation, body mass index (BMI) and smoking status. We will tabulate the estimates of the annual incidence of VTE including 95% confidence intervals for each calender window of the study period.

Documents

Study publications

Khialani D, Jones ME, Szépligeti SK, Ording AG, Ehrenstein V, Petersen I, van H...

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 source(s)

THIN® (The Health Improvement Network®)

Danish registries (access/analysis)

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

Electronic healthcare records (EHR)

Other

Data sources (types), other

Prescription event monitoring

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