Study of utilisation of combined hormonal contraceptives in Europe

First published: 22/10/2017
Last updated: 02/07/2024

Study | Finalised

Administrative details

PURI
https://redirect.ema.europa.eu/resource/40853

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 institution and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark
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02/04/2024

Institution

Educational Institution

ENCePP partner

University College London Leiden University, the Netherlands

Networks

Aarhus University Consortium (ad-hoc)

Contact details

Study institution contact
Vera Ehrenstein

Study contact

ve@clin.au.dk
Primary lead investigator

Henrik Toft Sørensen
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 data collection

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

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
500000

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

Data sources

Data source(s)
THIN® (The Health Improvement Network®)
Danish registries (access/analysis)

Data sources (types)
Administrative data (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