# Study of utilisation of combined hormonal contraceptives in Europe

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## 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 DEPARTMENT OF CLINICAL EPIDEMIOLOGY	
☐ Denmark	
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Institution	

# University College London Leiden University, the Netherlands

#### **Networks**

Aarhus University Consortium (ad-hoc)

## Contact details

**Study institution contact** 

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Study contact

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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 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)</li>
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)</li>

#### 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

## **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