# Study of regulatory communication and risk awareness following the Article 31 referral of Combined Hormonal Contraceptives in relation to thromboembolism

**First published:** 22/10/2017

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS21356

**Study ID**

26587

**DARWIN EU® study**

No

**Study countries**

Denmark

Slovakia

Spain

United Kingdom

**Study description**

This study uses surveys and questionnaires to study whether women and prescribers consider the risks of venous thromboembolism when making decisions about the use of combined hormonal contraceptives and what sources of information inform their assessments

**Study status**

Finalised

# Research institutions and networks

## Institutions

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

Denmark

**First published:** 20/07/2021

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Institution | Educational Institution

### Aarhus University & Aarhus University Hospital CLINICAL EPIDEMIOLOGY AND DATA SCIENCE,

## DEPARTMENT OF CLINICAL MEDICINE

Denmark

**First published:** 20/07/2021

**Last updated:** 20/10/2026

Institution | Educational Institution

## University College London United Kingdom

## Networks

## Aarhus University Consotrium (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: 21/06/2016

Actual: 21/06/2016

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**Study start date**
Planned: 30/01/2017

Actual: 30/01/2017

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**Date of final study report**
Planned: 23/01/2018

Actual: 07/02/2018

# Sources of funding

- EMA

# Study protocol

Study of regulatory communication and risk awareness.pdf (323.88 KB)

# Regulatory

**Was the study required by a regulatory body?**

Yes

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

Not applicable

# Methodological aspects

## Study type

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Not applicable

**If ‘other’, further details on the scope of the study**

Qualitative assessment

**Main study objective:**

1. To consider the extent to which women and health professionals are aware of the risks of venous thromboembolism (VTE) in users of combined hormonal contraceptives (CHC)2. To document awareness, knowledge, attitudes and practices related to recommendations from regulatory authorities3. To understand how advice from regulators concerning CHC, and specifically how the risks of VTE are perceived

## 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**

Prescribers and women of childbearing age (between 16 and 49 years of age)

**Age groups**

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

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**Special population of interest**

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

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**Estimated number of subjects**

1.200

## Study design details

**Data analysis plan**

Qualitative assessment of interviews and web survey results

## Documents

**Study results**

qualitative CHC - deliverable 3-final report - revised may18.pdf (1.49 MB)

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# 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**

Interviews, Web surveys

# 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