

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

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
DEPARTMENT OF CLINICAL EPIDEMIOLOGY

 Denmark

First published: 20/07/2021


Last updated: 02/04/2024

Institution

Educational Institution

ENCePP partner

Aarhus University & Aarhus University Hospital
DEPARTMENT OF CLINICAL EPIDEMIOLOGY

 Denmark

First published: 20/07/2021

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Institution

Educational Institution

ENCePP partner

University College London United Kingdom

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: 21/06/2016

Actual: 21/06/2016

Study start date

Planned: 30/01/2017

Actual: 30/01/2017

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

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

Not applicable

Methodological aspects

Study type

Study type list

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 authorities
3. 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
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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)
-

Special population of interest

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

Estimated number of subjects

1200

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)

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