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

PURI
https://redirect.ema.europa.eu/resource/26587

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 institution and networks

Institutions

Aarhus University & Aarhus University Hospital DEPARTMENT OF CLINICAL EPIDEMIOLOGY

Denmark
First published: 20/07/2021
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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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02/04/2024

Institution

Educational Institution

ENCePP partner

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

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 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

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

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