Prescription patterns of combined hormonal contraceptives with 3rd or 4th versus 2nd generation progestogens in France, Germany and the UK during 2002- 2011: A retrospective analysis of the IMS Disease Analyser databases

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Study Finalised

Administrative details

EU PAS number

EUPAS3712

Study ID

14169

DARWIN EU® study

No

Study countries

- [ ] France
- [ ] Germany
- [ ] United Kingdom

Study description

The PRAC is currently reviewing under Article 31 of Directive 2001/83/EC the risk of venous and arterial thromboembolic events and risk minimisation in users of all formulations of 3rd or 4th generation combined hormonal contraceptives. In the context of such a review, a comparative description of prescribing patterns of these medicinal products versus 2nd generation combined hormonal contraceptives in three large EU countries over a 10 year period can further inform on drug utilisation and thereby support regulatory decision-making from a public health perspective. This study aims to describe the prescription of 3rd or 4th versus 2nd generation progestogen-containing combined hormonal contraceptives in France, Germany and the UK in the period 2002-2011. The study includes women 15 - 49 years old who are recipients of at least one prescription of combined hormonal contraceptives containing 2nd, 3rd or 4th generation progestogens as recorded during the study period from 1st January 2002 to 31st December 2011 in the IMS Disease Analyser data of France, Germany and the UK. In each study country the number and proportion of women being prescribed 3rd or 4th versus 2nd generation combined hormonal contraceptives are computed and stratified by age, time in calendar years, and by ‘new user’ versus ‘switcher’.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

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Primary lead investigator

Annalisa Rubino

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 15/02/2013

Actual: 15/02/2013

Study start date

Planned: 18/02/2013

Actual: 18/02/2013

Date of final study report
Planned: 22/03/2013

Actual: 22/03/2013

Sources of funding

- EMA

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

The main objective of this analysis is to describe the pattern of prescriptions of 3rd or 4th versus 2nd generation progestogen-combined contraceptives in France, Germany and the UK in the period from 1st January 2002 to 31 December 2011.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Retrospective database analysis

Study drug and medical condition

Study drug International non-proprietary name (INN) or common name

LEVONORGESTREL

NORETHISTERONE

NORGESTREL

DESOGESTREL

GESTODENE

NORGESTIMATE

ETONOGESTREL

DROSPIRENONE

DIENOGEST

CHLORMADINONE

NOMEGESTROL

NORELGESTROMIN

Medical condition to be studied

Contraception

Population studied

Short description of the study population

Women 15 - 49 years old who are recipients of at least one prescription of combined hormonal contraceptives containing 2nd, 3rd or 4th generation progestogens as recorded during the study period from January 1, 2002 to December 31, 2011 in the IMS Disease Analyser data of France, Germany and the UK.

Age groups

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

Estimated number of subjects

1200000

Study design details

Data analysis plan

The analyses conducted are descriptive in nature. In each country the following was computed:• Proportion of women (all ages) receiving prescriptions for 3rd or 4th versus 2nd generation combined hormonal contraceptives stratified by 5 year age groups,• Proportion of women (15–49 years old) receiving prescriptions for 3rd or 4th versus 2nd generation combined hormonal contraceptives throughout the observation period and by calendar year 2002 through 2011.

Documents

Study, other information

EMA Analysis of IMS data on combined hormonal contraceptives.pdf (593.41 KB)

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), other

LifeLink EMR FR, IMS Disease Analyser Germany

Data sources (types)

Electronic healthcare records (EHR)

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