Cohort Study of Psychiatric Adverse Events Following Exposure to Levonorgestrel-Containing Intrauterine Devices in UK General Practice

First published: 29/08/2018

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Study Finalised

Administrative details

EU PAS number

EUPAS25373

Study ID

25374

DARWIN EU® study

No

Study countries

☐ United Kingdom

Study description

A cohort study performed to compare the incidence of anxiety, panic attacks, sleep problems or restlessness between groups of women who were new users of levonorgestrel-releasing and non-hormonal intrauterine devices.

Study status

Finalised

Research institutions and networks

Institutions

European Medicines Agency (EMA)

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Jim Slattery

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 27/03/2017

Actual: 27/03/2017

Study start date
Planned: 01/01/2000

Actual: 01/01/2000

Date of final study report
Planned: 21/05/2018

Actual: 21/05/2018

Sources of funding

- Other

More details on funding

European Commission

Study protocol

LNGIUD.protocolEMA (3).pdf(794.65 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:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Data collection methods:

Secondary use of data

Main study objective:

Exposure to a levonorgestrel-releasing intrauterine device has been associated with depression and, more recently, a connection to anxiety, panic attacks,

sleep problems and restlessness has been suggested. This study uses data from the THIN database of UK general practice to investigate these suggestions.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

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

LEVONORGESTREL

Medical condition to be studied

Anxiety

Panic attack

Sleep disorder

Restlessness

Population studied

Short description of the study population

Control group consists of women using IUDs not medicated with levonorgestrel (or other hormonal product).

Active arm of the study included women fitted with an levonorgestrel-releasing intrauterine devices and with more than one year of prior data collection in THIN.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

10000

Study design details

Outcomes

First occurrence of Read codes for anxiety, panic attacks, sleep problems and restlessness. For anxiety and sleep problems appropriate prescriptions of relevant treatments were also considered to indicate the condition. An analysis of depression as a positive control was included.

Data analysis plan

Hazard ratios for the first occurrence of psychiatric symptoms or prescriptions of disease-specific treatments will be calculated on an intention-to-treat basis using a proportional hazards model.

Documents

Study results

LNG Technical Report.pdf(1.05 MB)

Study publications

Slattery J, Morales D, Pinheiro L, Kurz X.Cohort Study of Psychiatric Adverse E...

Data management

Data sources

Data source(s)

THIN® (The Health Improvement Network®)

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

Unknown