Pharmacoepidemiological study (Drug Utilization Study) of JAYDESS use in routine clinical practice in Sweden (Jaydess DUS)

First published: 02/02/2015

Last updated: 22/02/2024

Study Finalised

Administrative details

EU PAS number

EUPAS8498

Study ID

33634

DARWIN EU® study

No

Study countries

☐ Sweden

Study description

The aim is to characterise new users of Jaydess and estimate duration of use and describe hormonal contraceptive methods prior to use of, and after discontinuing, Jaydess. The study will comprise a pilot study including users of Mirena and a main study including users of Jaydess. The main study will include 3 parts using different type and level of information from the national and regional registers. Validation will be carried out by comparing the information in the registers with that in the medical records for a randomly selected sample of the study population.

Study status

Finalised

Research institutions and networks

Institutions

Centre for Pharmacoepidemiology, Karolinska Institutet (CPE-KI)

Sweden

First published: 24/03/2010

Last updated: 23/04/2024

Institution **Educational Institution** **Laboratory/Research/Testing facility** **Not-for-profit** **ENCePP partner**

Contact details

Study institution contact

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Study contact

clinical-trials-contact@bayer.com

Primary lead investigator

Helle Kieler

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 02/09/2013

Actual: 15/05/2015

Study start date

Planned: 01/01/2017

Actual: 01/01/2017

Date of interim report, if expected

Actual: 25/10/2018

Date of final study report

Planned: 31/01/2023

Actual: 02/11/2022

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

JaydessDUSSweden_20140112 clean.pdf(283.64 KB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 3 (required)

Methodological aspects

Study type

Study type list

Study topic:

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Drug utilisation

Data collection methods:

Secondary use of data

Main study objective:

Study duration of use and indication for use of JAYDESS

Study Design

Non-interventional study design

Cohort

Other

Non-interventional study design, other

Observational, descriptive study

Study drug and medical condition

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

LEVONORGESTREL

Anatomical Therapeutic Chemical (ATC) code

(G03AC03) levonorgestrel

levonorgestrel

Population studied

Short description of the study population

The study population involved female patients, first time users of levonorgestrel contraceptive intrauterine system (JAYDESS), identified through Swedish national health registers (Prescribed Drug Register, the Patient Register and the Medical Birth Register) and the population register.

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Estimated number of subjects

10000

Study design details

Outcomes

- Duration of use of JAYDESS - Indication for use, - Age at insertion and removal

Data analysis plan

Simple descriptive statistics presenting means and proportions

Documents

Study results

16903_EU PAS Abstract_V1.0_2022-08-22.pdf(216.81 KB)

Study report

16903_Study Report_Redacted_V1.0_2022-08-22.pdf(5.19 MB)

Data management

Data sources

Data source(s)

Sweden National Prescribed Drugs Register / Läkemedelsregistret

Data source(s), other

Swedish national health registers (the Patient Register and the Medical Birth Register) and the population register, Stockholm regional and primary care databases, Medical records

Data sources (types)

Administrative healthcare records (e.g., claims)

Drug dispensing/prescription data

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