# 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





### Administrative details

**Study description** 

| EU PAS number    |  |
|------------------|--|
| EUPAS8498        |  |
| Study ID         |  |
| 33634            |  |
| DARWIN EU® study |  |
| No               |  |
| Study countries  |  |
| Sweden           |  |

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**



### Contact details

#### **Study institution contact**

### Helle Kieler clinical-trials-contact@bayer.com

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

### **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)

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**

| П | ln                                      | レ | n | $\sim$ | ۱۸ | n |
|---|---|---|---|--------|----|---|
| u | ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | ĸ |   | ( )    | w  |   |

### **Check completeness**

Unknown

### **Check stability**

Unknown

### **Check logical consistency**

Unknown

## Data characterisation

#### **Data characterisation conducted**

No