Active post-marketing surveillance of Levonorgestrel IUS insertion related difficulties: a non-interventional post-authorisation safety study

First published: 12/11/2014

Last updated: 23/04/2024

Study Finalised

Administrative details

EU PAS number

EUPAS7857

Study ID

26348

DARWIN EU® study

No

Study countries

Bulgaria

Czechia

Denmark

Hungary
Lithuania
Norway
Poland
United Kingdom

Study description

The PASS STUDY is an observational study with primary objective to characterize, under routine practice, the ease of insertion and the safety profile of Levonorgestrel IUS during insertion in a study population that is representative of the actual users of the IUS (either new user and patients switching from Mirena). And with secondary objective to characterize the utilization pattern for Levonorgestrel IUS. The Data Clarification Form (DCF) will be included in the Levonorgestrel IUS package. The doctors will be asked to complete and send it to the sponsor on spontaneous basis.

Study status

Finalised

Research institutions and networks

Institutions

Gedeon Richter

First published: 01/02/2024

Last updated: 01/02/2024

Institution

Multiple centres: 200 centres are involved in the study

Study timelines

Date when funding contract was signed
Planned: 15/10/2014

Actual: 15/10/2014

Study start date
Planned: 16/10/2014

Actual: 16/10/2014

Date of final study report
Planned: 21/12/2020

Actual: 28/08/2020

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Gedeon Richter Plc

Study protocol

Levosert Pass Study Amend 02 140618.pdf (602.49 KB)

Levosert PASS Protocol Amendment_5 2.pdf (3.66 MB)

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

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Safety study (incl. comparative)

Data collection methods:

Primary data collection

Main study objective:

The primary objective of this PASS is to characterize, under routine practice, the ease of insertion and the safety profile of Levonorgestrel IUS during insertion in a study population that is representative of the actual users of the IUS (either new users and patients switching from Mirena).

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Multinational, multi-centre, PASS study

Study drug and medical condition

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

LEVONORGESTREL

Medical condition to be studied

Abnormal uterine bleeding

Population studied

Short description of the study population

The study focused on women who had prescribed with levonorgestrel intrauterine system (IUS) for any indication as a part of routine care.

Inclusion criteria:

1. Willing and able to provide written informed consent
2. Prescribed levonorgestrel IUS as part of routine clinical care prior to enrolment.

Exclusion criteria:

1. There are no exclusion criteria for this study.

Age groups

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

Estimated number of subjects

1000

Study design details

Outcomes

IUS insertion related adverse events, The indication of use of levonorgestrel IUS

Data analysis plan

DCF information will be entered in the Clinical and, partially, in the Pharmacovigilance databases. Details of treatment initiation and prescribing reasons as reported on the questionnaire will be provided using descriptive statistics. Prescribing pattern will be assessed. The reported insertion problems will be provided in a listing which will also be part of the Final Clinical Study

Report. General comments about the readability of the instructions for use and handling will be recorded for potential future improvements.

Documents

Study publications

Velev R.; A multiple center, randomised, parallel group, single-blind clinical ...

Trinh XB, Talma WA, Makar AP, Buytaert G, Weyler J, van Dam PA, Use of the levo...

Mawet M, Nollevaux F, Nizet D, Wijzen F, Gordenne V, Tasev N, Segedi D, Marines...

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 sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

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