European Active Surveillance Study of LCS12 (EURAS-LCS12)

First published: 12/05/2014

Last updated: 23/04/2024

Study Ongoing

Administrative details

EU PAS number

EUPAS6476

Study ID

45939

DARWIN EU® study

No

Study countries

- [ ] Austria
- [ ] Finland
- [ ] France
- [ ] Germany
- [ ] Italy
- [ ] Poland

- [ ] Spain
- [ ] Sweden
- [ ] United Kingdom

Study description

Intrauterine systems (IUS) have a high contraceptive efficacy. LCS12 is a new IUS which contains levonorgestrel. Because there is a lack of comparative data between LCS12 and Mirena (and copper IUDs), it remains unclear whether there are differences in contraceptive failure rates between LCS12 and either Mirena or copper IUDs. In addition, any transcervical procedure is potentially associated with the risk of infection/inflammation. The primary objective is to determine whether LCS12 is associated with a higher risk of unintended pregnancy compared to Mirena and compared to copper IUDs. Secondary objectives are the investigation of pelvic inflammatory disease (PID), uterine perforations and ectopic pregnancies. The study also aims to capture the drug utilization pattern of LCS12 and established IUDs during routine clinical practice, outcomes of unintended pregnancies, risk of serious adverse events, difficulties associated with IUD insertion, cervical conization procedures, and neuropsychiatric disorders/disturbances (since 2017). In the course of the study, another hormonal IUD ('Kyleena') was launched which has the same dimensions as LCS12, but a higher LNG content, and is approved for use up to 5 years. The initial LNG release rates are approximately 14 µg/24h for LCS12, 20 µg/24h for Mirena and 17.5 µg/24h for Kyleena. New users of Kyleena were continuously enrolled in the study since the market introduction and are categorized as 'other hormonal IUD'. However, with increasing usage of Kyleena and enrolment into the EURAS-LCS12 study, the SMAC endorsed inclusion of Kyleena as an official cohort to the study to better understand current routine clinical practice. As comparative data on contraceptive failure between Kyleena and Mirena based on routine clinical practice are not available at present, the comparison of contraceptive failure rates between Kyleena and Mirena / copper

IUDs was added as an additional secondary outcome to the EURAS-LCS12 study.

Study status

Ongoing

Research institutions and networks

Institutions

Berlin Center for Epidemiology & Health Research, ZEG Berlin

Germany

First published: 06/08/2019

Last updated: 20/06/2024

Institution **Laboratory/Research/Testing facility** **ENCePP partner**

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Klaas Heinemann

Primary lead investigator

Study timelines

Date when funding contract was signed
Actual: 18/12/2013

Study start date
Planned: 01/06/2014

Actual: 02/06/2014

Date of final study report
Planned: 30/09/2027

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

EURAS-LCS12_Protocol_FINAL_2014_02_21.pdf (905.98 KB)

LCS12_StudyProtocol_V04.00_Amend 5_V02-00_20211105-clean.pdf (2.58 MB)

Regulatory

Was the study required by a regulatory body?

Yes

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

EU RMP category 1 (imposed as condition of marketing authorisation)

Other study registration identification numbers and links

https://clinicaltrials.gov/ct2/show/NCT02146950

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Effectiveness study (incl. comparative)

Main study objective:

The main objective of this study is to assess the effectiveness and safety of LCS-12 in real life in new users as compared to Mirena and compared to copper

IUDs.

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

Contraception

Pelvic inflammatory disease

Uterine perforation

Ectopic pregnancy

Population studied

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Estimated number of subjects

83000

Study design details

Outcomes

Yes, the primary clinical outcome of interest for the short- and long-term follow-up is: - Unintended pregnancy, Yes, secondary clinical outcomes of interest are - Ectopic pregnancy, - Pelvic inflammatory disease (PID) - Uterine perforations - Unintended pregnancies in users of Kyleena compared with users of Mirena and with users of copper IUDs

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Data analysis plan

Based on the similarities between LCS12 and Mirena, the a priori assumption is that use of LCS12 is not associated with an increased risk of unintended pregnancy compared to Mirena. Furthermore, it is expected that the risk is lower or equal to copper IUDs. A non-inferiority design was chosen to investigate contraceptive failure rate of LCS12. The primary analysis will be based on the comparison of the upper confidence limit for the point estimate of the contraceptive failure hazard ratio with the predefined non-inferiority limit. Multivariate techniques such as Cox regression will be used to take into consideration the influence of confounding. A more sophisticated analysis method (i.e. regression analyses based on propensity scores) will also be applied. Similar analyses are applied for the comparison between Kyleena, Mirena and copper IUDs.

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.

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

Declaration of Interests_LCS12.pdf (1.5 MB)

Composition of steering group and observers

SMAC_LCS12.pdf (174.13 KB)

SMAC_LCS12_updated.pdf (68.44 KB)

Signed code of conduct

2014-0026-Declaration of Compliance-SDPP-6476.pdf (453.96 KB)

Signed code of conduct checklist

2014-0026-Checklist Code of Conduct-SDPP-6476.pdf (566.77 KB)

Signed checklist for study protocols

2014-0026-Checklist Study Protocol-SDPP-6476.pdf (266.36 KB)

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