

# 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

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### Study ID

45939

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### DARWIN EU® study

No

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### Study countries

- Austria
- Finland
- France
- Germany
- Italy
- Poland

- Spain
  - Sweden
  - United Kingdom
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## **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.

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### Study status

Ongoing

## Research institutions and networks

### Institutions

Berlin Center for Epidemiology & Health Research,  
ZEG Berlin

Germany

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Institution

Laboratory/Research/Testing facility

ENCePP partner

## Contact details

### Study institution contact

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Study contact

[l.eggebrecht@zeg-berlin.de](mailto:l.eggebrecht@zeg-berlin.de)

### Primary lead investigator

Klaas Heinemann

## Study timelines

### **Date when funding contract was signed**

Actual: 18/12/2013

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### **Study start date**

Planned: 01/06/2014

Actual: 02/06/2014

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### **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

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## 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

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#### **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

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### **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)
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### **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)

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### **Composition of steering group and observers**

[SMAC\\_LCS12.pdf](#) (174.13 KB)

[SMAC\\_LCS12\\_updated.pdf](#) (68.44 KB)

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### **Signed code of conduct**

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

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### **Signed code of conduct checklist**

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

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### **Signed checklist for study protocols**

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

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## Data sources

### **Data sources (types)**

[Other](#)

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### **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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No