# Study on the association of uterine perforation and intrauterine device (IUD) expulsion with breastfeeding status at the time of IUD insertion and postpartum timing of IUD insertion in electronic medical record databases. A postmarketing requirement for Mirena (APEX IUD)

**First published:** 04/02/2020

**Last updated:** 02/07/2024

Study Finalised

## Administrative details

**EU PAS number**

EUPAS33461

**Study ID**

38003

**DARWIN EU® study**

No

**Study countries**

United States

**Study description**

This study is an US postmarketing requirement that investigates the outcomes of uterine perforation and intrauterine device (IUD) expulsion in association with breastfeeding, postpartum exposures and type of IUD.The study aims to quantify the risk of uterine perforation and IUD expulsion in relation to the breastfeeding status and postpartum time (≤ 6, > 6 ≤ 14, > 14, ≤ 52 or > 52 weeks postpartum, including women without a recorded delivery within the past 52 weeks) at the time of IUD insertionThis study will also assess the risk of both perforation and expulsion by type of IUD. The effect of IUD types (LNG-releasing vs. copper) on the association between perforation/ expulsion and breastfeeding status/ postpartum status, as well as the effect of breastfeeding status on the association between perforation and/or expulsion and postpartum status are also investigated.

**Study status**

Finalised

# Research institutions and networks

## Institutions

### RTI Health Solutions (RTI-HS)

France

Spain

Sweden

United Kingdom

United Kingdom (Northern Ireland)

United States

**First published:** 21/04/2010

**Last updated:** 11/08/2026

Institution | Not-for-profit | ENCePP partner

Kaiser Permanente Northern California Oakland, USA, Kaiser Permanente Southern California Pasadena, USA, Kaiser Permanente Washington Seattle, USA, Regenstrief Institute Indianapolis, USA

## Contact details


**Study institution contact**

Bayer Clinical Trials Bayer AG Clinical-Trials-Contact@bayer.com

Study contact

Clinical-Trials-Contact@bayer.com

**Primary lead investigator**

Bayer Clinical Trials Bayer AG

Primary lead investigator

## Study timelines

**Date when funding contract was signed**
Planned: 29/06/2016

Actual: 29/06/2016

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**Study start date**
Planned: 01/12/2018

Actual: 03/12/2018

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**Date of final study report**
Planned: 30/04/2020

Actual: 03/03/2020

## Sources of funding

- Pharmaceutical company and other private sector

## More details on funding

Bayer AG

## Study protocol

19682_Study Protocol_v1.0_2019-06-29_Redacted.pdf (708.64 KB)

## Regulatory

**Was the study required by a regulatory body?**

Yes

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

Non-EU RMP only

## Other study registration identification numbers and links

CT.gov: NCT03754556Bayer No.: 19682

# Methodological aspects

## Study type

## Study type list

**Study topic:**

Disease /health condition

Human medicinal product

**Study type:**

Non-interventional study

**Scope of the study:**

Assessment of risk minimisation measure implementation or effectiveness

**Data collection methods:**

Secondary use of data

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**Main study objective:**

1. To compare the risk of uterine perforation among women who were breastfeeding versus women who were not breastfeeding at the time of first IUD insertion2. To evaluate the risk of uterine perforation among women who had their first IUD insertion within different time periods postpartum, including women without a recorded delivery

## Study Design

**Non-interventional study design**

Cohort

## Study drug and medical condition

**Medicinal product name, other**

Mirena

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**Anatomical Therapeutic Chemical (ATC) code**

(G02BA03) plastic IUD with progestogen

plastic IUD with progestogen

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**Medical condition to be studied**

Uterine perforation

Device expulsion

## Population studied

**Short description of the study population**

The study population will be women with evidence of insertion of an IUD during the study period who were no more than 50 years of age at the time of the insertion. Only women with available EHR records from 12 months before the day of IUD insertion and onward will be included in this study.

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**Age groups**

- Adolescents (12 to < 18 years)
- Adults (18 to < 46 years)
- Adults (46 to < 65 years)

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**Special population of interest**

Women of childbearing potential not using contraception

Women of childbearing potential using contraception

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**Estimated number of subjects**

225.000

# Study design details

**Outcomes**

Person-time at risk / Confirmed date of uterine perforation / Confirmed date of IUD-expulsion, Incidence rate & Cumulative incidence rate of uterine perforation or IUD expulsion / Incidence of difficult IUD-insertion / Adjusted hazard ratio of uterine perforation or IUD-expulsion / Adjusted incidence rate ratio (IRR) & Adjusted incidence rate difference (IRD) of uterine perforation or IUD expulsion / Effect modification for uterine perforation or IUD expulsion

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**Data analysis plan**

Descriptive analyses for all variables of interest will be presented overall and stratified by database. For categorical variables, frequencies and percentages will be presented for each level. For continuous variables, the mean, standard deviation, minimum, maximum, median, and quartiles will be presented. For estimates, two-sided 95% confidence intervals will be calculated.Crude incidence rates and cumulative incidence of the outcomes will be estimated for each exposure group.Crude hazard ratios will be calculated for each outcome without adjustment for covariates within each database. Confounding adjustment will be performed via overlap weighting. Adjusted hazard ratios will be calculated accounting for the propensity score–based weighting approach.Effect estimates across datasources will be estimated. Analyses of the adjusted hazard ratios for the two primary objectives combined will include hypothesis testing using two-sided statistical test.

## Documents

**Study results**

19682_CSR abstract_v1.0_2020-11-11.pdf (356.07 KB)

# 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.

**Conflicts of interest of investigators**

19682_CSR_v1.0_2020-11-11_Redacted.pdf (9.37 MB)

# Data sources

**Data sources (types)**

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