Incidence and Trend of Ectopic Pregnancy 2009-2018 - A population-based Study

First published: 12/02/2020

Last updated: 23/04/2024

Study Finalised

Administrative details

PURI

https://redirect.ema.europa.eu/resource/46964

EU PAS number

EUPAS33562

Study ID

46964

DARWIN EU® study

No

Study countries

☐ United States

Study description

The overall goal of this retrospective cohort study is to assess the incidence rate of ectopic pregnancy over the last decade in a representative population of US women and assess potential risk factors associated with ectopic pregnancy. The research will utilize Kaiser Permanente electronic health records to assess whether ectopic pregnancy incidence rates have changed over the last decade overall as well as in women using prescription contraceptive methods of interest including in IUDs, OCPs and DMPA. The objectives of the study are: - To describe the incidence and temporal trends of ectopic pregnancy during the past decade in women of reproductive age and in subpopulations with selected prescriptive contraceptive use, in particular hormonal and non-hormonal IUDs. - To describe demographic and clinical risk factors associated with ectopic pregnancy and to determine the accuracy of data from electronic health records for assessing prescribed contraceptive method over time.

Study status

Finalised

Research institutions and networks

Institutions

Bayer AG

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Institution

Kaiser Permanente Northern California Oakland, USA, Kaiser Permanente Southern California Pasadena, USA

Contact details

Study institution contact

Bayer Clinical Trials Bayer AG

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: 30/06/2018

Actual: 27/06/2018

Study start date

Planned: 01/12/2018

Actual: 01/12/2018

Date of final study report

Planned: 15/11/2021

Actual: 15/11/2021

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Bayer AG

Study protocol

Study 20257_Study Protocol_Amendment_Redacted_V2_10_28_2020.pdf(955.04 KB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Other study registration identification numbers and links

CT.gov: NCT03670784,Bayer number: 20257

Methodological aspects

Study type

Study topic:

Disease /health condition

Study type:

Non-interventional study

Scope of the study:

Disease epidemiology

Other

If ‘other’, further details on the scope of the study

Accuracy of electronic health data

Data collection methods:

Secondary use of data

Main study objective:

The overall goal of this study is to assess the incidence rate of ectopic pregnancy over the last decade in a representative population of US women and potential risk factors associated with ectopic pregnancy.

Study Design

Non-interventional study design

Cohort

Cross-sectional

Study drug and medical condition

Medical condition to be studied

Ectopic pregnancy

Population studied

Short description of the study population

The study will take place within health care systems with EHR data in California. The study population will include women enrolled in the health plans of the two systems who were age 15 to 44 years from January 1, 2009 to December 31, 2018.

Age groups

Adolescents (12 to < 18 years)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

2000000

Study design details

Outcomes

Number of ectopic pregnancies / Person-time at risk, Risk factors for ectopic pregnancies / Accuracy of electronic health data to identify a) the diagnosis of ectopic pregnancy, b) the contraceptive method at time of diagnosis of ectopic pregnancy, c) the contraceptive method over time and d) induced abortions /

Numbers of ectopic pregnancies managed surgically / Numbers of ectopic pregnancies managed medically

Data analysis plan

Descriptive analyses for all variables of interest will be presented overall and within each database for the study cohort. For categorical variables, frequencies and percentages will be presented for each level. Continuous variables will be summarized by the mean, standard deviation, minimum, maximum, median, and quartiles. For estimates, two-sided 95% confidence intervals will be calculated. The proportion of missing data will be captured for each variable. Demographic and clinical characteristics of patients experiencing the following outcomes will be presented: Ectopic pregnancies, Surgically treated, Medically treated, and Unknown/other (includes expectant management) Characteristics will include frequencies and percentages for each level of each outcome and by demographics and clinical characteristics of patients at the index date.

Documents

Study results

20257_EU_PAS_Abstract_Redacted_V1.0_2022-02-23.pdf(337.99 KB)

Data management

ENCePP Seal

Conflicts of interest of investigators

20257_Study_Report_Redacted_V1.0_2022-02-23.pdf(2.62 MB)

Data sources

Data sources (types)

Administrative healthcare records (e.g., claims)

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