Maternal and Newborn Safety profile of Progestogens in Early Pregnancy (PEARLY)

First published: 29/10/2021

Last updated: 27/05/2024

Study Finalised

Administrative details

EU PAS number

EUPAS43631

Study ID

45156

DARWIN EU® study

No

Study countries

- ☐ China
- ☐ Russian Federation
- ☐ Türkiye

Study description

This multinational, prospective, active surveillance, registry study following two cohorts will include study participants (aged 18 to 35) who are pregnant and seeking any type of medical treatment, including dydrogesterone and other progestogens, for either (A) recurrent pregnancy loss and/or bleeding in early pregnancy or (B) as IVF/ART support. Pregnant women not taking progestogen and are advised an alternative non-medical treatment, in the context of bleeding in early pregnancy, recurrent pregnancy loss, or undergoing natural cycle frozen embryo transfer (NC-FET) can also be included in this study. Eligible study participants will be recruited via an international network of prescribing Health Care Practitioners (HCPs) in China, Turkey, and Russia with the aim to collect data related to maternal safety and newborn safety in women prescribed progestogens during early pregnancy. Study participants will be followed from early pregnancy until 6 – 12 weeks after giving birth. All malformations will be captured via direct contacts with the study participants. Study participants will be sent online questionnaires via the electronic Patient Reported Outcomes (ePRO) solution provided by MediData. Major malformations reported by the study participants will be validated by ZEG Berlin via relevant source documents and if necessary, via contacting the treating HCPs. The total study duration is planned for approximately 4 years including recruitment and follow-up. The study was terminated due to challenges in recruitment.

Study status

Finalised

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**

Networks

Drug Treatment and Women's Health (EURAS/INAS)

- Austria
- Belgium
- Czechia
- Finland
- France
- Germany
- Hungary
- Italy
- Netherlands
- Poland
- Spain
- Sweden
- Switzerland
- United Kingdom

First published: 14/09/2018

Last updated: 20/08/2024

Network

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Clare Barnett

Primary lead investigator

Study timelines

Date when funding contract was signed

Planned: 31/03/2021

Actual: 31/03/2021

Study start date

Planned: 10/12/2021

Actual: 15/12/2021

Date of final study report

Planned: 29/11/2024

Actual: 04/10/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Abbott Products Operations AG

Study protocol

PEARLY_StudyProtocol_V02-00_ENCePP.pdf(1.27 MB)

Regulatory

Was the study required by a regulatory body?

No

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

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Disease epidemiology

Main study objective:

Assess the rate of major malformations in fetus and newborns by indication and by exposure to progestogens during the first trimester of pregnancy, with an emphasis on dydrogesterone versus non-dydrogesterone treatments.

Study Design

Non-interventional study design

Other

Non-interventional study design, other

Observational Registry

Population studied

Age groups

Preterm newborn infants (0 – 27 days)

Term newborn infants (0 – 27 days)

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

11000

Study design details

Outcomes

Rate of major malformations in fetus and newborns by indication and by exposure to progestogens during the first trimester of pregnancy, with an emphasis on dydrogesterone versus non-dydrogesterone treatments, • Describe the rate of other malformations by progestogen type and indication of use, • To describe demographic, reproductive, and maternal health data, as well as available information on prenatal diagnostics and pregnancy outcome for the mother and the newborn.

Data analysis plan

The risk of major malformation as compared between treatment cohorts will be assessed by unconditional logistic regression. Potential factors of influence, potential confounding factors or risk factors, will be considered either in a pre-analysis step regarding cohort balancing using methods based on propensity scores, e.g. inverse probability of treatment weighting (IPTW) or by subsequent inclusion into the logistic model as cofactors for adjustment of the treatment effect. Crude and adjusted OR and 95% confidence intervals (CI) will be estimated. The primary analysis cohorts are defined as pregnant women using (I) dydrogesterone during the first trimester versus (II) other treatment and/or treatment combinations and/or no treatment during the first trimester of pregnancy. The overall incidence of major malformation will be calculated with respect to all pregnancies observed in the respective cohort and compared per

indication area.

Documents

Study results

PEARLY_FinalStudyReportsV01-00_redacted.pdf(2.17 MB)

Data management

ENCePP Seal

This study has been awarded the ENCePP seal

Conflicts of interest of investigators

PEARLY_DeclarationOfInterest.pdf(902.75 KB)

Composition of steering group and observers

PEARLY_SMAC_Composition.pdf(55.46 KB)

Signed code of conduct

empty_file_1.pdf(11.35 KB)

Signed code of conduct checklist

empty_file_1.pdf(11.35 KB)

Signed checklist for study protocols

empty_file_1.pdf(11.35 KB)

Data sources

Data sources (types)

Disease registry

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