The PRIDE-Asthma cohort: insight into the short- and long-term effects of asthma and asthma medication during pregnancy

First published: 06/07/2023

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Study Ongoing

Administrative details

PURI

https://redirect.ema.europa.eu/resource/105751

EU PAS number

EUPAS105750

Study ID

105751

DARWIN EU® study

No

Study countries

☐ Denmark

☐ Netherlands

☐ Norway

☐ Sweden

Study description

Approximately 8% of pregnant women have asthma, making it one of the most common chronic conditions during pregnancy. As particularly women with poor levels of asthma control are at increased risk of adverse outcomes, international recommendations emphasize the importance of adequate pharmacological treatment. Multiple studies using large population-based databases, however, have shown that dispensing rates for asthma medication decline during pregnancy, suggestive of non-adherence and/or discontinuation of asthma medication. The objectives of this study are threefold: 1) To develop and validate a questionnaire to assess adherence to asthma medication use during pregnancy. 2) To assess reasons for self-initiated discontinuation of asthma medication and changes in asthma medication use during pregnancy. This includes assessment of trajectories of asthma control throughout pregnancy and identification of factors that are associated with improvements and deteriorations. 3) To initiate a focus cohort of at least 250 pregnant women with asthma to support this project and future studies on the short- and long-term safety of asthma medication during pregnancy. A multinational, cross-sectional study will be conducted for objective 1. The focus cohort for objectives 2 and 3 will be embedded in the PRIDE Study, an ongoing prospective cohort study among pregnant women and their offspring, with follow-up throughout childhood. Pregnant women with asthma will be asked to complete four Web-based asthma-specific questionnaires (at enrollment in the focus cohort, at gestational weeks 23 and 35, and 2 months post-partum), the Asthma Control Questionnaire (every four weeks throughout pregnancy and two times post-partum), and a medication diary (throughout pregnancy and 2 months post-partum). In addition, consent is asked to obtain data on medical history (GP and

pulmonologist) and medication use (pharmacy).

Study status

Ongoing

Research institutions and networks

Institutions

Department for Health Evidence, Radboud university medical center (Radboudumc)

Netherlands

First published: 30/06/2022

Last updated: 26/06/2023

Institution | **Educational Institution** | **Hospital/Clinic/Other health care facility** | **ENCePP partner**

Pharmacoepidemiology and Drug Safety Research Group (PharmaSafe), University of Oslo

Norway

First published: 19/10/2016

Last updated: 08/11/2016

Institution | **Educational Institution** | **ENCePP partner**

Contact details

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Primary lead investigator

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Primary lead investigator

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Study timelines

Date when funding contract was signed

Planned: 01/01/2020

Actual: 01/11/2021

Study start date

Planned: 01/09/2023

Actual: 01/01/2024

Date of final study report

Planned: 01/07/2026

Sources of funding

- Non-for-profit organisation (e.g. charity)

More details on funding

Stichting Astmabestrijding

Study protocol

PRIDE-Astma_protocol_version1.2.pdf(250.47 KB)

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 topic:

Disease /health condition

Human medicinal product

Study type:

Non-interventional study

Scope of the study:

Assessment of risk minimisation measure implementation or effectiveness

Drug utilisation

Data collection methods:

Primary data collection

Main study objective:

1) To design and validate a questionnaire to assess adherence to asthma medication use during pregnancy. 2) To assess reasons for self-initiated discontinuation of asthma medication and changes in asthma medication use during pregnancy. 3) To enable future studies on the short- and long-term effects of maternal asthma and the use of asthma medication during pregnancy.

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Medical condition to be studied

Asthma

Population studied

Age groups

Adults (18 to < 46 years)

Special population of interest

Pregnant women

Estimated number of subjects

500

Study design details

Outcomes

1) Level of adherence to asthma medication and factors associated with adherence. 2) Trajectories of level of asthma control throughout pregnancy, 1) Common pregnancy complications 2) Common adverse birth outcomes 3) Child respiratory health until the age of 6 years

Data analysis plan

Evaluation of novel scale to assess adherence: validity analysis (PCA), reliability analysis (internal consistency), construct validity. Associations with factors related to adherence: univariable and multivariable linear and logistic regression analyses. Trajectories of level of asthma control: unsupervised clustering methods. Short- and long term effects of asthma and asthma medication use during pregnancy: risk estimation.

Data management

Data sources

Data sources (types)

Disease registry

Electronic healthcare records (EHR)

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