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

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Denmark



# Administrative details

PURI
https://redirect.ema.europa.eu/resource/105751
EU PAS number
EUPAS105750
Study ID
105751
DARWIN EU® study
No
Study countries

Netherlands
Norway
Sweden

#### **Study description**

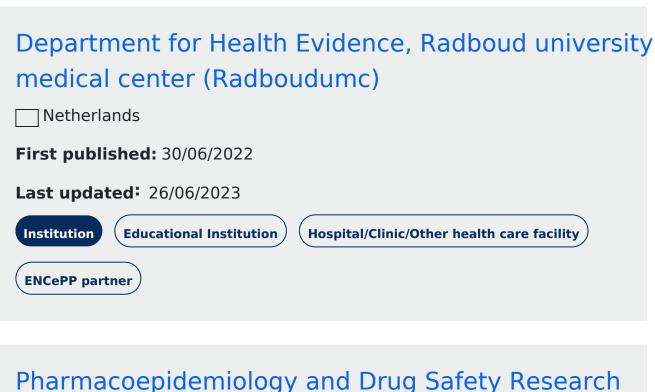
Approximately 8% of pregnant women have asthma, making it one of the most common chronic conditions during pregnancy. As particularly women with poor levels of asthma control are at increased risk of adverse outcomes, international recommendations emphasize the importance of adequate pharmacological 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 longterm safety of asthma medication during pregnancy. A multinational, crosssectional 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 Webbased 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 postpartum), and a medication diary (throughout pregnancy and 2 months postpartum). In addition, consent is asked to obtain data on medical history (GP and

#### **Study status**

Ongoing

# Research institutions and networks

#### **Institutions**



Pharmacoepidemiology and Drug Safety Research	
Group (PharmaSafe), University of Oslo	
Norway	
First published: 19/10/2016	
<b>Last updated:</b> 08/11/2016	
Institution Educational Institution ENCePP partner	

# Contact details

#### **Study institution contact**

Marleen van Gelder

Study contact

Marleen.vanGelder@radboudumc.nl

#### **Primary lead investigator**

Marleen van Gelder

**Primary lead investigator** 

#### **ORCID** number:

0000-0003-4853-4434

# 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