

# Asthma during pregnancy

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<b>Registration date</b> 30/11/2023	<b>Overall study status</b> Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 28/11/2023	<b>Condition category</b> Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Asthma is the most common chronic disease during pregnancy. Pregnancy is recognized as a major challenge in the management of asthma as it can alter the course of asthma severity and its treatment, which in turn can affect pregnancy outcomes. Uncontrolled asthma is associated with adverse perinatal outcomes, as pre-term birth and low birth weight and increased maternal complications, as pre-eclampsia. Therefore asthma during pregnancy needs active management. Although existing studies show sufficient evidence for the relation between suboptimal asthma control in pregnancy and adverse outcomes the question remains how to optimize care for this large group of patients. To that end we need to identify subgroups of pregnant asthma patients at high risk of adverse outcomes who might benefit from more intensive monitoring and personalized treatment during pregnancy.

### Who can participate?

All pregnant women (>18 year) with a doctor diagnosis of asthma referred to the asthma pregnancy outpatient clinic of the HAGA teaching Hospital.

### What does the study involve?

All subjects enrolled in the database will have to give written informed consent before their data can be entered. Subjects enrolled in the study will receive routine medical care as per standard guidelines. No additional interventions, beyond the standard care outlined in this protocol, will be administered to the subjects participating in the study.

### What are the possible benefits and risks of participating?

Patients participating in the study will receive close monitoring and regular medical care from the respiratory physician and respiratory nurse. This may lead to early detection and management of health/pregnancy issues. By taking part in this study, patients are helping to develop new knowledge about how to optimise the care of pregnant patients with asthma. This could benefit future generations.

Because the design of this study is observational and non-interventional it does not involve the potential risk of administration of experimental treatments or interventions.

### Where is the study run from?

HAGA Ziekenhuis (The Netherlands)

When is the study starting and how long is it expected to run for?  
February 2017 to September 2028

Who is funding the study?  
Investigator initiated and funded

Who is the main contact?  
Sarah Bendien, s.vannederveen@hagaziekenhuis.nl

## Contact information

### Type(s)

Public, Scientific, Principal Investigator

### Contact name

Ms Sarah Bendien

### ORCID ID

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### Contact details

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## Additional identifiers

### EudraCT/CTIS number

Nil known

### IRAS number

### ClinicalTrials.gov number

Nil known

### Secondary identifying numbers

METC nr 17-113

## Study information

### Scientific Title

Asthma during pregnancy, an observational prospective cohort study

### Study objectives

It is unclear how to optimise the care of pregnant patients with asthma in clinical practice

## **Objectives**

1. To study clinical and functional characteristics of pregnant women with asthma referred to secondary care, to study a possible relationship between these characteristics and asthma control or level of asthma treatment at first consultation and to evaluate follow-up after first consultation.
2. To identify subgroups of pregnant asthma patients at high risk of adverse outcomes who might benefit from more intensive monitoring and personalized treatment during pregnancy.

## **Ethics approval required**

Ethics approval not required

## **Ethics approval(s)**

Ethics approval was waived by the Human Research Ethics Committee METC Zuidwest Holland (nr 17-113)

## **Study design**

Non-interventional observational prospective cohort study

## **Primary study design**

Observational

## **Secondary study design**

Cohort study

## **Study setting(s)**

Hospital

## **Study type(s)**

Other

## **Participant information sheet**

## **Health condition(s) or problem(s) studied**

Asthma, pregnancy

## **Interventions**

This is a single-centre, non-interventional, prospective observation cohort study.

First consultation: lung function, questionnaires and laboratory testing.

Patients start by seeing a respiratory nurse for inhalation technique, compliance, and education.

Subsequently patients are seen by one of two asthma- specialized respiratory physicians.

Asthma diagnosis is checked and medication is intensified or decreased, based on asthma symptoms and (eosinophilic) airway inflammation. Education is given about medication, lifestyle (smoking, obesity and exercise) and the importance of asthma control during pregnancy.

Each patient is seen by the gynecologist within 3 weeks after first consultation.

After this all patients are presented in a multidisciplinary team meeting (MDT)

Standard follow up is 4-8 weeks after first consultation accompanied by: ACQ (asthma control questionnaire questionnaire) and FeNO (fractional exhaled nitric oxide) and or spirometry.

After this second consultation, further follow up depends on the current clinical condition and the conclusions of the MDT.

Maternal and fetal outcomes and delivery parameters are collected from the medical records after delivery.

## **Intervention Type**

Other

## **Primary outcome measure**

1. 6 item ACQ (asthma control questionnaire questionnaire) at visit 1 (baseline) and 2
2. 32 item AQLQ (asthma quality of life questionnaire) at visit 1
3. 6 item HCU (health care utilization questionnaire) at visit 1
4. 5 item pregnancy asthma control test
5. Lung function measurements; FEV1, FVC and FEV1/FVC measures by Spirometry at baseline, and visit 2 only when indicated by the attending healthcare provider (respiratory physician)  
FeNO measurement at visit 1 and visit 2
6. Asthma exacerbations during pregnancy (by reviewing the electronic patient file and dispensing data from patients and hospital pharmacy) (Severe asthma exacerbations were defined by at least one of the following criteria:
  - 6.1. Patient reported use of OCS courses (if not on maintenance OCS)
  - 6.2. Patient reported doubling of maintenance dose of OCS for at least 3 days
  - 6.3. Patient reported unscheduled emergency visits or hospitalization for asthma exacerbation), poorly controlled maternal asthma during pregnancy (measured by ACQ and the pregnancy asthma control test)
7. Adverse pregnancy outcomes (maternal and perinatal outcomes); pre-eclampsia, pregnancy induced hypertension, low birth weight, pre term delivery, small for gestational age, perinatal mortality, admission on neonatal ICU, congenital malformations. Maternal and fetal outcomes and delivery parameters are collected from the medical records after delivery. For those patients who are no longer in our care, information is requested from their treating general practitioner or midwife.

## **Secondary outcome measures**

There are no secondary outcome measures

## **Overall study start date**

01/02/2017

## **Completion date**

01/09/2028

# **Eligibility**

## **Key inclusion criteria**

All pregnant women (>18 years) with a doctor's diagnosis of asthma referred to the asthma pregnancy outpatient clinic of the HAGA teaching Hospital.

## **Participant type(s)**

Patient

## **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Female

**Target number of participants**

250

**Key exclusion criteria**

1. Non pregnant
2. Not referred to secondary care

**Date of first enrolment**

01/09/2018

**Date of final enrolment**

01/09/2026

## **Locations**

**Countries of recruitment**

Netherlands

**Study participating centre****HAGA Ziekenhuis**

Department of Pulmonology

STZ Centre of Excellence for severe Asthma

HAGA Teaching Hospital

Els Borst-Eilersplein 275

The Hague

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## **Sponsor information**

**Organisation**

Haga Hospital

**Sponsor details**

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**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.hagaziekenhuis.nl/home/>

**ROR**

<https://ror.org/03q4p1y48>

## **Funder(s)**

**Funder type**

Other

**Funder Name**

Investigator initiated and funded

## **Results and Publications**

**Publication and dissemination plan**

Dissemination among colleagues during international conferences such as ERS, EAACI and ISAF by for example poster sessions or abstract presentations  
Planned publication in a high-impact peer-reviewed journal

**Intention to publish date**

01/09/2028

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study will be available upon request from [s.vannederveen@hagaziekenhuis.nl](mailto:s.vannederveen@hagaziekenhuis.nl)

**IPD sharing plan summary**

Available on request