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Asthma during pregnancy

Submission date	Recruitment status	[ ] Prospectively registered
12/10/2023	Recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
30/11/2023	Ongoing	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
28/11/2023	Pregnancy and Childbirth	[ ] 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

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Protocol serial number
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

Study type(s)
Other

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(s)
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.

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
Female

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
Netherlands
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Sponsor information

Organisation
Haga Hospital

ROR
https://ror.org/03q4p1y48

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

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

IPD sharing plan summary

Available on request