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# Risk of deep venous thrombosis and pulmonary embolism in severe asthma

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| **Submission date**<br>09/11/2011 | **Recruitment status**<br>No longer recruiting | [_] Prospectively registered<br>[_] Protocol<br>[_] Statistical analysis plan<br>[_] Results<br>[_] Individual participant data<br>[_] Record updated in last year |
| **Registration date**<br>30/11/2011 | **Overall study status**<br>Completed | |
| **Last Edited**<br>29/10/2015 | **Condition category**<br>Respiratory | |

**Plain English summary of protocol**

Background and study aims
Asthma is one of the most common long-term lung diseases. Most asthma can be controlled with inhaled corticosteroids and bronchodilators. Venous thromboembolism (VTE) is a serious, potentially fatal, condition where a blood clot forms in a vein. The aim of the study is to find out whether the risk of venous thromboembolism is increased in severe asthma and whether this is related to asthma severity and the use of corticosteroids.

Who can participate?
Patients aged over 18 with asthma.

What does the study involve?
The patients are asked to complete a questionnaire about their history of VTE, history of asthma and medication use. The results are then compared with a comparable reference general population. Because sex and age have a large influence on the incidence of VTE, the reference general population is matched by sex and age.

What are the possible benefits and risks of participating?
There are no known risks to participants.

Where is the study run from?
Academic Medical Centre, Amsterdam, The Netherlands
Medical Centre Leeuwarden, Leeuwarden, The Netherlands
Dutch high altitude Asthma Centre Davos, Switzerland
The study is coordinated by the Academic Medical Centre Amsterdam

When is the study starting and how long is it expected to run for?
December 2010 to May 2011

Who is funding the study?
Dutch Asthma Foundation

Who is the main contact?
Mr C.J. Majoor
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# Contact information

### Type(s)
Scientific

### Contact name
Mr C Majoor

### Contact details
Meibergdreef 9
Amsterdam
Netherlands
1105 AZ

# Additional identifiers

### Protocol serial number
Astmafonds 3.2.11.021

# Study information

### Scientific Title
Risk of deep venous thrombosis and pulmonary embolism in severe asthma: an observational study

### Study objectives
1. The prevalence of venous thromboembolism (VTE) is increased in patients with severe asthma as compared to the general population
2. The prevalence of VTE increases with severity of asthma
3. Use of corticosteroids is associated with increased prevalence of VTE in patients with asthma

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
The questionnaire was qualified as no overburden for the patient. Therefore no Medical Ethics Committee approval was needed.

### Study design
Open label observational cross-sectional study

### Primary study design
Observational

### Study type(s)
Other

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

### Interventions
All patients will complete a questionnaire about:
1. History of deep venous thrombosis (DVT) and pulmonary embolism (PE)
2. History of asthma
3. Medication use
The results of all included patients will be compared with a comparable reference general population (Naess IA, et al. J Thromb Haemost 2007 April;5(4):692-9). Because sex and age have a large influence on the incidence of DVT and pulmonary embolism (PE), the reference general population will be matched to sex and age for all patients. The study population will be compared with the reference general population by indirect standardisation.

### Intervention Type
Other

### Phase
Not Applicable

### Primary outcome(s)
Cumulative number of first DVT and PE events during lifetime as compared to the sum of the expected cumulative hazards of first DVT and PE events from all patients in an age- and sex-matched general population

### Key secondary outcome(s))
Hazard ratio for PE and DVT of of asthma associated factors (like oral and inhalational corticosteroids, atopy, duration of asthma, age of onset)

### Completion date
01/05/2011

## Eligibility

### Key inclusion criteria
1. Age 18-88 years old
2. Patients recruited from outpatient clinics from the Academic Medical Centre Amsterdam, Medical Center Leeuwarden and the Dutch High Altitude Asthma Clinic, Davos, Switzerland
3. Confirmed diagnosis of asthma according to Global Initiative for Asthma (GINA) 2010 guidelines
4. Diagnosis of severe asthma according to the international consensus 2009 (IMI-UBIOPRED)

### Participant type(s)
Patient

### Healthy volunteers allowed
No

### Age group
Adult

### Lower age limit
18 years

### Upper age limit
88 years

### Sex
All

### Key exclusion criteria
1. Severe co-morbidities that could interfere with coagulation (Including cancer, other severe inflammatory diseases and human immunodeficiency virus (HIV)
2. Severe psychiatric illness

### Date of first enrolment
01/12/2010

### Date of final enrolment
01/05/2011

## Locations

### Countries of recruitment
Netherlands

### Study participating centre
**Meibergdreef 9**
Amsterdam
Netherlands
1105 AZ

## Sponsor information

### Organisation
Astmafonds (Netherlands)

### ROR
https://ror.org/00ddgbf74

## Funder(s)

**Funder type**
Research organisation

**Funder Name**
Astmafonds (Netherlands) (ref: 3.2.11.021)

# Results and Publications

## Individual participant data (IPD) sharing plan

### IPD sharing plan summary
Not provided at time of registration

### Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---|---|---|---|---|---|
| Participant information sheet | Participant information sheet | 11/11/2025 | 11/11/2025 | No | Yes |