

Risk of deep venous thrombosis and pulmonary embolism in severe asthma

Submission date 09/11/2011	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/11/2011	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 29/10/2015	Condition category Respiratory	<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 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

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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