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Risk of deep venous thrombosis and pulmonary embolism in severe asthma

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

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

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 measure
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

Secondary outcome measures
Hazard ratio for PE and DVT of of asthma associated factors (like oral and inhalational corticosteroids, atopy, duration of asthma, age of onset)

Overall study start date
01/12/2010

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

Age group
Adult

Lower age limit
18 Years

Upper age limit
88 Years

Sex
Both

Target number of participants
550 (275 mild/moderate asthma and 275 severe asthma patients)

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)

Sponsor details
Postbus 627
Amersfoort
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3800 AP

Sponsor type
Research organisation

Website
http://www.astmafonds.nl/

ROR
https://ror.org/00ddgbf74

Funder(s)

Funder type
Research organisation

Funder Name
Astmafonds (Netherlands) (ref: 3.2.11.021)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration