PRedicting Outcome using systemic Markers In Severe Exacerbations of COPD - The PROMISE-COPD Cohort Study

Published: 30-06-2008
Last updated: 07-05-2024

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Observational invasive

Summary

ID

NL-OMON31901

Source
ToetsingOnline

Brief title
Systemic makers in severe exacerbations of COPD

Condition

- Bronchial disorders (excl neoplasms)

Synonym
chronic bronchitis, COPD, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Alkmaar
Source(s) of monetary or material Support: geen subsidie;alleen geringe vergoeding voor logistiek

Intervention

Keyword: biomarkers, COPD, exacerbation, prognosis

Outcome measures

Primary outcome

• Number of exacerbations during two-year follow-up, including exacerbations requiring hospitalization and exacerbations managed by the primary care physicians

• Number of deaths of any cause during the two-year follow-up

• Number of respiratory-related deaths during the two-year follow-up

• Time to next exacerbation, time to next exacerbation requiring hospitalization and time to death during the two-year follow-up

Secondary outcome

• Length of stay during hospitalization

• Admission and length of stay in intensive care unit

• Need for intubation or non-invasive ventilation

• Need for oral steroids and antibiotics

• Quality of life assessed by Saint Georges Respiratory Questionnaire and SF-36

• Dyspnoea and respiratory symptoms as assessed by the MMRC and LRTI-VAS

• Lung function and 6-minute walk test changes

Study description

Background summary

Chronic obstructive pulmonary disease (COPD) is a growing cause of morbidity and mortality. Exacerbations are now recognized as important events in the

natural course of disease progression consuming enormous health care resources. There is scarce information about biomarkers able to predict exacerbations during the stable state of the disease and the clinical outcome of the exacerbations

Study objective

We aim to (1) describe the 4 weeks course of clinical, laboratorial, and lung function parameters during exacerbations of COPD as compared to the stable state of the disease; (2) explore predictors that might identify recurrence and poor outcome in the stable state and during exacerbations; (3) analyze the potential of circulating biomarkers for the diagnosis and prognosis of COPD in the stable state and during exacerbations, including a correlation with the number of hospitalizations and death of any cause; (4) assess whether easily to determine circulating biomarkers are capable to replace the widely accepted BODE index as predictor of long term prognosis in COPD; (5) analyze the impact of viral and bacterial infections as well as pulmonary embolism on in-hospital and long-term clinical outcomes.

Study design

A total of 600 patients with moderate to very severe COPD (GOLD II-IV) willing to take part in a longitudinal, cohort study will be recruited from lung function laboratory records of university hospitals. Patients will be instructed to contact the study site in case of exacerbation of respiratory symptoms leading to physician contact. Clinical information including quality of life, sputum, lung function test, exercise capacity, and blood samples will be obtained at inclusion in the study and at two-year follow-up. Patients will be invited to attend at total of 4 scheduled visits (6 months, 12 months, 18 months and 24 months). Additionally, clinical information, sputum and blood samples will be collected during episodes of acute exacerbation. In cases of acute exacerbation requiring hospitalisation, systematic routine work-up including chest-X-rays, facultative thoracic CT-scans, facultative bronchoalveolar lavage and facultative echocardiography will be recommended. Predictive factors for exacerbation and outcome will be explored using univariate and multivariate Cox proportional hazard models.

Study burden and risks

RISKS OF STANDARD PROCEDURES BEING DONE FOR PURPOSES OF THE RESEARCH WHICH YOU
MIGHT NOT NEED TO HAVE IF YOU WERE NOT IN THE STUDY
- Discomfort of a puncture
- The lung function test might be tiring for some patients
- Six-minute walk test might be tiring for some patients
- Additive radiation exposure due to chest X-ray and if neccessary CT scan.

Uncommonly, the use of contrast medium (CT scan) might be associated with a decreased kidney function. Some patients might experience discomfort during the examination (claustrophobia)
- Bronchoscopy(faculative) causes cough and dyspnea during the procedure
- The patient has to fill in 2 questionnaires and 2 lists with symptoms before each visit

BENEFITS
You may benefit directly from being in this research study because your health status is being checked on a regular basis. Moreover, your participation may help others with this condition in the future as a result of knowledge gained from the research.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

• Age above 40 years;
• Smoking history >= 10 pack years;
• Moderate to very severe COPD (GOLD II to IV);
• Currently stable disease (at least 4 weeks after resolution of the last exacerbation);
• Willingness to participate in a longitudinal, cohort study;
• Willingness of the family physician to have the patient included in a cohort study;
• Written informed consent.

Exclusion criteria

• Rapid fatal disease;
• Pulmonary condition other than COPD as the main respiratory disease, e.g. bronchiectasis, asthma or pulmonary fibrosis;
• Immunosuppression including HIV, organ transplantation or chronic steroid use (more than 10mg prednisolone-equivalent per day);
• Patients unable and unwilling to give written informed consent;
• Muskulo-skeletal process preventing ambulation.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-09-2008
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	30-06-2008
Application type:	First submission
Review commission:	METC Noord-Holland (Alkmaar)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
Other	ISRTCN
CCMO	NL22085.094.08