Prospective cohort study of COPD patients from Maastricht area: the Maastricht COPD Cohort (MCC)

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Ethical review	Not approved
Status	Will not start
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON38812

Source
ToetsingOnline

Brief title
Maastricht COPD Cohort

Condition

- Respiratory disorders NEC

Synonym
chronic bronchitis, emphysema

Research involving
Human

Sponsors and support

Primary sponsor: CIRO+, expertisecentrum voor chronisch orgaanfalen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, Exacerbation, Rehabilitation, Respiratory infection

Outcome measures

Primary outcome

- The role of respiratory infections as pathogenic component of COPD exacerbations;

- The individual response to respiratory pathogens associated with COPD exacerbations;

- Determination and validation of the COPD phenotypes;

- The natural history of systemic manifestations and co-morbidities of COPD and their interrelationships, associated to exacerbations;

- The long-term effects of pulmonary rehabilitation;

- The impact of exacerbations during pre-rehabilitation and post-rehabilitation on health outcomes;

- Short- and long-term mortality.

Secondary outcome

- Formation of a prospective cohort of COPD outpatients at the department of Respiratory Medicine in Maastricht.

Study description

Background summary

COPD is a burdensome chronic disease, which has a huge impact on patient*s life. Many experience exacerbations, which are acute deteriorations of the disease and reduce the quality of life, speed the disease progression and increase the risk of death. Despite the intense research efforts, many

clinically important questions are still un-answered. These questions include:
*Why are some patients susceptible to COPD exacerbations and others not? What is the role of respiratory infections in this, and how does this affect the disease progression?
Pulmonary rehabilitation (PR) is recognized as a core-component in the management of patients with COPD, not only in the stable state, but also following treatment for an acute exacerbation. The long-term benefits of pulmonary rehabilitation on patient-related outcomes and exacerbations are currently unknown. Furthermore, the impact of recurring exacerbations on these long-term effects are to be researched.

Study objective

The primary aim of this project is to define the role exacerbations play in the pathophysiology of COPD. Moreover, the study has the aim to determine the long-term effects of PR and the natural course of the disease. The unique design of MCC will enable to study these and future hypotheses using the same patient cohort.

Study design

A prospective single-centre observational cohort study.

Study burden and risks

All patients will have a baseline assessment, possibly as part of the revalidation. They will have a regular follow-up every three months and when admitted to the hospital for exacerbations. When hospitalised, follow-up takes place after 28 days.

Tests can have side effects, think of bruises when taking blood, fatigue during some tests, or an allergic reaction at a CT-scan. However, these tests are being used in daily practice, so no additional risks are expected.

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

- Adults, either sex, older than 40 years of age;
- Smoking history of 10 Pack Years or more;
- Diagnosis of COPD stages I-IV as defined by the Global initiative for chronic Obstructive Lung Disease (GOLD);
- Classified by COPD severity in group B or D, based on the GOLD criteria of COPD severity (Figure 1);
- Patients must be able to complete diaries and quality of life questionnaires;
- Patients must sign and date an informed consent prior to inclusion in the MCC.

Exclusion criteria

- Progressively fatal disease, or life expectancy *6 months;
- Women who are breast feeding or are pregnant;
- Patients with mental conditions rendering them unable to understand the nature, scope, and possible consequences of the study;
- Patients unlikely to comply with the protocol, e.g., uncooperative attitude, inability to return for follow-up visits, and unlikelihood of completing the study;
- Patients participating in an intervention study.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	200
Type:	Anticipated

Ethics review

Not approved

Date:	24-06-2013
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
CCMO	NL43896.068.13
Other	Onderzoek wordt geregistreerd zodra goedkeuring is ontvangen (op www.trialregister.nl)