Low dose-CT for differentiation between AECOPD and pneumonia. An effective tool for diagnosis?

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To determine the true prevalence of pneumonia in exacerbating COPD patients by low-dose CT

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON44303

Source
ToetsingOnline

Brief title
Maastricht COPD CT study (MCCT)

Condition

- Respiratory disorders NEC

Synonym
acute exacerbation COPD, acute lungattack COPD

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: afd. longziekten MUMC; centraal diagnostisch laboratorium MUMC; Thermo Fisher Scientific,Thermo Fisher Scientific

Intervention

Keyword: COPD, exacerbation, low dose-CT, pneumonia

Outcome measures

Primary outcome

To determine the true prevalence of pneumonia in exacerbating COPD patients as analysed by low dose-CT

Secondary outcome

- To determine clinical and/or biochemical predictors (PCT) for pneumonia in COPD patients proven by low dose-CT;

- To describe additional pulmonary pathology evidenced by low dose-CT;

- Phenotype COPD exacerbations based on outcomes of low dose-CT (standardized assessment).

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, it remains difficult to differentiate exacerbations from pneumonia*s in patients with COPD. A more comprehensive tool is required, to diagnose and phenotype exacerbations and guide treatment, in order to avoid *mistreatment* as much as possible. Low-dose CT has been shown to be more sensitive in detecting pneumonia in COPD patients compared to standard chest x-ray. Procalcitonin is a serum biomarker that has been succesfully used to shorten antibiotic treatment in COPD exacerbations and is currently being evaluated as a prognostic marker for bacterial infections.

Study objective

To determine the true prevalence of pneumonia in exacerbating COPD patients by

low-dose CT

Study design

A prospective single-centre cohort study.

Study burden and risks

The burden of the research will be very low, as procedures take place during hospital admission. Additionally, a low dose-CT will be performed, as well as two extra bloodsamples (combined with a blood sample for treatment purposes). Both procedures won't take a lot of extra time, and are daily used in clinical practice. Moreover, three questionnaires will be taken. Estimated risk is very low.

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, class A-D, as defined by the Global initiative for chronic Obstructive Lung Disease (GOLD);
• Doctor*s diagnosis of AECOPD (clinical presentation of a patient complaining of an acute change of symptoms that is beyond normal day-to-day variation - baseline dyspnoea, cough and/or sputum production);
• Patients must sign and date an informed consent prior to inclusion in the study.

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 participating in an intervention study which influences outcomes;
• Un-ability to lie flat for the performance of CT-scan.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	29-02-2016
Enrollment:	202
Type:	Actual

Ethics review

Approved WMO Date:	25-03-2015
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	23-05-2016
Application type:	Amendment
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

ID: 26796
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL49554.068.14
Other	Onderzoek wordt geregistreerd zodra goedkeuring is ontvangen (op www.trialregister.nl)
OMON	NL-OMON26796

Study results

Date completed:	30-08-2018
Actual enrolment:	5

Summary results

Trial ended prematurely