Hyperinflation in COPD exacerbations

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON40607

Source
ToetsingOnline

Brief title
Hyperinflation in COPD exacerbations

Condition

- Respiratory tract infections

Synonym
Chronic Obstructive Pulmonary Disease, COPD, lung emfysema and chronic bronchitis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COPD, Dynamic, exacerbation, hyperinflation

Outcome measures

Primary outcome

Temporal relation between changes in hyperinflation (as measured by inspiratory capacity) during resolution of the exacerbation, and changes in HR-QoL and dyspnoea.

Secondary outcome

Other HR-QoL and dyspnea patient report outcomes (PRO)'s

Lung function parameters: dynamic hyperinflation, TLC, diffusion, FEV1, FVC, IOS, single breath nitrogen washout.

Enose for measurement of exhaled organic compounds

Inflammation parameters measured by blood sample and nasopharyngeal swab

Infection as assessed by routine lab and cultures

Length of stay in the hospital

Study description

Background summary

COPD exacerbations are the main driver of quality of life in COPD, of survival, and of more than 50% of costs incurred in COPD. The latter is above all due to exacerbations leading to hospitalisation. It is therefore surprising that not much research has been performed regarding COPD exacerbations requiring hospitalisation. Among others, it is unclear why some patients require a longer hospital treatment than others. For individual patients, dyspnea is the most important complaint during an exacerbation, but this is relatively difficult to measure and correlates poorly with many more readily measured parameters that change during an exacerbation. For instance. the differences in both the level and course of breathlessness during an exacerbation of COPD do not associate well with the classical parameters that are affected by an exacerbation such as blood oxygen saturation or lung function. It is well known that dyspnea in a stable situation is much stronger correlated with hyperinflation than with oxygen saturation and lung function. We postulate that this increased

hyperinflation is also a strong determinant of the dyspnea as present during exacerbations.
Bacterial and viral infections both can induce a COPD exacerbation. The first cells in the line of defense against these infectious agents are the epithelial cell layers. It may well be that the course of an exacerbation is also related to changes in the defense mechanisms of eptihelial cells. Therefore more studies are needed investigating epithelial responses to inhaled stimuli in e.g. cell cultures and measurements of released cytokines and proteins, as well as gene-expression profiling. Furthermore epithelial responses can be measured with ENOS in vivo that unbiasedly measures exhaled organic compounds. Finally, steroids are the mainstay of treatment of COPD exacerbations, yet differential response to steroids may affect the outcome as well. Thus we will additionally investigate steroid responses in vivo and compare this with epithelial responses in vitro by epithelial cell cultures of the same individuals. In summary, more knowledge about exacerbations is needed to help understand why certain patients need to be hospitalized as opposed to others , and what drives their length of stay.

Study objective

Objective: The main objective is to establish the strength of the relationship between improvements in dyspnea and health related Quality of Life (HR-QoL) with the decrease in hyperinflation during the resolution of a COPD exacerbation in the hospital. The secondary objectives are to assess whether dynamic changes in airway inflammation and patency, especially in the small airways, contribute to changes in hyperinflation. Furthermore, whether the level and course of hyperinflation, airway epithelial pro-inflammatory response, epithelial response to steroids, genome-wide gene-expression profiles and the changes thereof, relate to quality of life and to length of hospital stay in COPD patients requiring hospitalisation for an exacerbation.

Study design

This is a single center cohort study, designed to asses COPD patients admitted with a COPD exacerbation. A total of 30 COPD patients with an exacerbation will be included in this study.

Study burden and risks

Patients will receive all necessary care and treatments as per normal routine. Participants will encounter some additional measurements mostly during the hospitalization, and once at the routine follow-up visit after hospitalization. There are broadly three groups of measurements: those to be performed as much as possible within 24 hours of admission; those to be performed several times during hospitalization, and those to be performed once, as soon as possible during hospitalization. Most measurements will be repeated at the routine

follow-up visit in stable state, approximately 6 weeks after the start of the hospitalization.

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

Male or Female, 40 years or older
Doctor*s diagnosis of COPD.
Experiencing an exacerbation of COPD requiring hospitalization at the moment of inclusion. An exacerbation is defined as a worsening of respiratory symptoms from the stable state and beyond normal day-to-day variations, which requires additional treatment.
Patients must be able to understand and complete protocol requirements, Instructions and questionnaires in Dutch
Written Informed consent

Exclusion criteria

If any of these criteria are absent at admission, but occur during the course of the study, patients will be followed up within the protocol as much as possible.
Pneumonia confirmed with X ray
COPD exacerbation requiring (non) invasive ventilation or admittance to an intensive care unit
Patient who received any investigational new drug within the last 4 weeks prior to admission or twice the duration of the biological half-life of any investigational new drug (whichever is longer).
Unstable angina pectoris or other clinically important cardiac co-morbidity requiring admission on a cardiology ward

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	18-09-2014
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	16-05-2014
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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: 22305
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL46407.042.14
OMON	NL-OMON22305