Gevangen lucht tijdens een longaanval

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22305

Source
Nationaal Trial Register

Health condition

COPD, Exacerbations, hospital, hyperinflation, dynamic, small airways, airway inflammation, Quality of Life, airway epithelial pro-inflammatory response, genome-wide gene-expression profile, epithelial response to steroids

Sponsors and support

Primary sponsor: UMCG
Source(s) of monetary or material Support: UMCG

Intervention

Outcome measures

Primary outcome

The changes in hyperinflation (as measured by inspiratory capacity) during resolution of the COPD exacerbation, and changes in HR-QoL (primary: CCQ) and dyspnea (Borg score)).

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

NA

Study 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

Day 1,2,3,4,5,6,7 discharge and day 42

Intervention

None

Contacts

Public
UMCG
H.A.M. Kerstjens
University Medical Center Groningen (UMCG),

Department of Respiratory Medicine
Postbox 30.001
Groningen 9700 RB
The Netherlands
+31 (0)50 3612357
Scientific
UMCG
H.A.M. Kerstjens
University Medical Center Groningen (UMCG),
Department of Respiratory Medicine
Postbox 30.001
Groningen 9700 RB
The Netherlands
+31 (0)50 3612357

Eligibility criteria

Inclusion criteria

- Male or Female, 40 years or older

- Doctor¡¦s diagnosis of COPD

- Incompletely reversible airflow obstruction defined as: 1) a post-bronchodilator FEV1/FVC < 70% and 2) FEV1 < 80% predicted. If patients have no readily available lung function measurement at admittance, but do have a clear doctors diagnosis of COPD, it is allowable to take the day 42 measurements of lung function.

- 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 provided in Dutch

- Written informed consent

Exclusion criteria

- 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 to a cardiology ward.

If any of these criteria were absent at admission, but occur during the course of the study, patients will be followed up within the protocol as much as possible.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	25-05-2014
Enrollment:	30
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	17-05-2014
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 40607
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4403
NTR-old	NTR4600
CCMO	NL46407.042.14
OMON	NL-OMON40607

Study results

Summary results
https://www.dovepress.com/static-and-dynamic-hyperinflation-during-severe-acute-exacerbations-of-peer-reviewed-article-COPD