Gevangen lucht tijdens een longaanval

Gepubliceerd: 17-05-2014 Laatst bijgewerkt: 15-05-2024

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Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22305

Bron
Nationaal Trial Register

Aandoening

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

Ondersteuning

Primaire sponsor: UMCG
Overige ondersteuning: UMCG

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)).

Toelichting onderzoek

Achtergrond van het onderzoek

NA

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-05-2014
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	17-05-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 40607
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

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