The effect of pulmonary rehabilitation in COPD: Dynamic hyperinflation and systemic inflammation during daily activities.

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON27345

Bron
Nationaal Trial Register

Aandoening

COPD

Ondersteuning

Primaire sponsor: Radboud University Nijmegen Medical Centre, Department of Pulmonary diseases
Overige ondersteuning: Radboud University Nijmegen Medical Centre, Department of Pulmonary diseases
Astmafonds
AstraZeneca

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Dynamic hyperinflation;
2. Dyspnea;
3. Biomarkers of systemic inflammation after ADL.

Dynamic hyperinflation and other respiratory impairments during ADL will be measured using the Oxycon Mobile (Viasys Healthcare, Germany), which is a portable breath-by-breath system, consisting of a face mask with turbine volume transducer and integrated O2 and CO2 gas analyzers. Subjects will be asked to rate their shortness of breath using a 10-point Borg scale at start and end of each ADL. Systemic inflammation will be characterized by measuring the number of circulating leukocytes (standard laboratory tests), and plasma levels of interleukins.

Toelichting onderzoek

Achtergrond van het onderzoek

This study will focus on the effect of pulmonary rehabilitation on respiratory impairments, dyspnea and systemic inflammation during ADL. 13 patients with COPD enter the 10 week outpatient pulmonary rehabilitation program and 13 patients will receive usual COPD care without rehabilitation. Before and after the rehabilitation or (10 weeks during) control period an ADL test will be performed and respiratory impairments will be measured using a portable breath-by-breath system. In addition, before and after ADL, blood will be collected that will be used for determination of biomarkers of systemic inflammation.

Doel van het onderzoek

It is hypothesized that in patients with COPD pulmonary rehabilitation will reduce respiratory impairments like dynamic hyperinflation and dyspnea during daily activities compared to control patients. Furthermore, rehabilitation will reduce the systemic inflammatory response induced by ADL.

Onderzoeksopzet

Before and after rehabilitation or control period:

1. Before daily activity (rest);

2. Immediately after daily activity.

Onderzoeksproduct en/of interventie

The multidisciplinary outpatient pulmonary rehabilitation program consists of a 10-week training program with 2 hour sessions, 3 times a week. The pulmonary rehabilitation program also includes education sessions and psychosocial support or nutritional intervention if necessary.
As a control group, COPD patients from the same hospital will be included. They receive usual COPD care which might include education, nutritional intervention if necessary, but no supervised physical exercise training.

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Stable COPD GOLD I-III;

2. Dynamic hyperinflation during ADL.

Belangrijkste redenen om niet deel te kunnen nemen

(Exclusiecriteria)

1. Long term oxygen therapy at home;

2. Severe ADL-limiting cardiac or neuromuscular disease;

3. Co-existing lung disease other than COPD;

4. Other inflammatory diseases;

5. Treatment with systemic anti-inflammatory drugs;

6. Previous participation in rehabilitation program (<2 year).

Extra exclusion criterium for control COPD patients:

1. Participation in supervised physical therapy program.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2012
Aantal proefpersonen:	26
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	20-08-2012
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL3436
NTR-old	NTR3587
CCMO	NL25920.091.08
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A