Fatigue in patients with Chronic Obstructive Pulmonary Disease (COPD)

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Fatigue is increased in patients with COPD compared to healthy elderly. Moderate to severe fatigue occurs frequently in clinically stable COPD (30-70%), and fatigue is next to dyspnoea the most dominant symptom in COPD. So, fatigue is a common,...

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

Samenvatting

ID

NL-OMON23962

Bron
NTR

Verkorte titel
FAntasTIGUE

Aandoening

Patients with Chronic Obstructive Pulmonary Disease (COPD); fatigue; underlying factors.

Ondersteuning

Primaire sponsor: Board of Directors Ciro
Overige ondersteuning: Lung Foundation, The Netherlands

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fatigue severity, measured by the subjective fatigue subscale of the Checklist Individual Strength (CIS-Fatigue).

Toelichting onderzoek

Achtergrond van het onderzoek

Fatigue is increased in patients with COPD compared to healthy elderly. Moderate to severe fatigue occurs frequently in clinically stable COPD (30-70%), and fatigue is next to dyspnoea the most dominant symptom in COPD. So, fatigue is a common distressing symptom in patients with COPD but goes often undiagnosed and untreated. The pathobiology of fatigue is complex and is thought to be caused by a cascade of events. Currently, the underlying causes of fatigue in COPD have been studied scarcely. To identify physical, systemic, psychological, and behavioural factors that precipitate and/or perpetuate fatigue in patients with clinically stable COPD and to identify the impact of exacerbation-related hospitalizations on fatigue and its perpetuating factors. Thirdly, to better understand the association between fatigue and 2-year all-cause hospitalization and mortality in patients with COPD.

Doel van het onderzoek

Fatigue is increased in patients with COPD compared to healthy elderly. Moderate to severe fatigue occurs frequently in clinically stable COPD (30-70%), and fatigue is next to dyspnoea the most dominant symptom in COPD. So, fatigue is a common, distressing symptom in COPD patients, and goes often undiagnosed and untreated. The pathobiology of fatigue is complex and is thought to be caused by a cascade of events. Currently, the underlying causes of fatigue have been studied scarcely in COPD.

The primary objectives of the FAntasTIGUE study are: (1) To chart the course of fatigue in patients with COPD; (2) To identify physical, systemic, psychological, and behavioural factors that precipitate and/or perpetuate fatigue in patients with COPD; (3) To identify the impact of exacerbation-related hospitalizations on fatigue and its perpetuating factors; (4) To better understand the association between baseline fatigue and 2-year all-cause hospitalization and mortality in patients with COPD.

The secondary objective of this study is: To identify diurnal differences in fatigue by augmenting traditional questionnaire data with Ecological Momentary Assessment (EMA).

Onderzoeksopzet

The assessments at baseline, 12 months, and during the first days of a possible exacerbation-related hospitalization will be performed in a hospital setting. The remaining measurements at 4, 8, 18, and 24 months will take place at the patients’ homes.

The primary outcome fatigue severity will be assessed at baseline, and at 4, 8, 12, 18 and 24 months, as well as during exacerbation-related hospitalizations and two weeks after discharge. The secondary outcome, day-to-day/diurnal variation in fatigue, will be registered at baseline, and at 4, 8 and 12 months. The precipitating and perpetuating factors of moderate to severe fatigue in patients with COPD (physical, psychological, behavioural, and systemic factors), will be assessed at baseline and at 12 months. Also, when patients are admitted to the hospital between baseline and 12 months due to an exacerbation of COPD, some tests will be repeated during the first days of hospitalization, and two weeks after discharge. At last, at 18 and 24 months the participants will be followed-up on their fatigue, number of exacerbations, exacerbation-related hospitalization and survival.

Onderzoeksproduct en/of interventie

Observational study to investigate the underlying factors of moderate to severe fatigue in patients with Chronic Obstructive Pulmonary Disease (COPD).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In order to be eligible to participate in this study, a subject must be diagnosed with COPD according to the Global Strategy for the Diagnosis, Management, and Prevention of COPD (GOLD), no use of oral corticosteroids and/or antibiotics; and/or has no exacerbation-related hospitalization less than 4 weeks before enrolment, and must provide written informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Patients lacking a sufficient understanding of the Dutch language and/or participating in concurrent intervention studies will be excluded.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2018
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-01-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 53067
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6722
NTR-old	NTR6933
CCMO	NL60484.100.17
OMON	NL-OMON53067

Resultaten

Samenvatting resultaten
N.a.