Fatigue in patients with Chronic Obstructive Pulmonary Disease (COPD)

No registrations found.

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

Summary

ID

NL-OMON23962

Source
Nationaal Trial Register

Brief title
FAntasTIGUE

Health condition

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

Sponsors and support

Primary sponsor: Board of Directors Ciro
Source(s) of monetary or material Support: Lung Foundation, The Netherlands

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

Day-to-day/diurnal variations of fatigue, measured by Ecological Momentary Assessment (EMA). EMA will be administered 8 times per day for 5 consecutive days at random intervals. The questions will assess momentary experiences that are context-dependent and/or likely fluctuate across a day or days.

Socio-demographic factors: gender, age (only at baseline), social-economic status (only at baseline), marital status, and survival status (baseline, month 4, 8, 12).

Physical factors body mass index, activity-related dyspnoea (mMRC) (baseline, month 4, 8, and 12), symptoms checklist using Visual Analogue Scale, lower-limb muscle function using a hand-held dynamometer (MicroFET2), history of COPD-related exacerbations and hospitalizations in the previous year (baseline, month 4, 8, and 12), current pulmonary and non-pulmonary medication, self-reported comorbidities (Charlson Comorbidity Index), waist circumference, peripheral arterial disease (Huntleigh D900 Doppler 8 Mhz probe), mobility (Short Physical Performance Battery), handgrip muscle strength (JAMAR), functional exercise capacity (6 Minute Walking Test (6MWT), combined with continuous monitoring of a patients' SpO2 and heart rate by the use of a pulse oximeter), bioelectrical impedance analysis, and lung function (post-bronchodilator spirometry, whole body plethysmograohy, and transfer factor for carbon monoxide - only at baseline).

Psychological factors: disease specific and generic health-status (Nijmegen Clinical Screening Instrument), COPD status (COPD Assessment Test) (baseline, month 4, 8, and 12), Generic Health status (EQ-5D-5L), symptoms of anxiety and depression (HADS) (baseline, month 4, 8, and 12), cognitive status (Montreal Cognitive Assessment), grief (Acceptance of Disease and Impairments Questionnaire), qualitative experience of fatigue (KWAMOE), fatigue-related self-efficacy (Self-Efficacy-5), catastrophizing (Jacobsen Fatigue Catastrophizing Scale), fear of progression (Fear Of Progression Questionnaire), Activity Cognitions Instrument (ACI), Patient Activation Measure (PAM).

Behavioural factors: smoking status, alcohol consumption, caffeine consumption, objectified physical activity (ActiGraph GT9X Link), sleep quality (Pittsburgh Sleep Quality Index + accelerometer-based sleep quality), drowsiness (Epworth Sleepiness Scale), attribution (Causal Attribution List), Impact on daily life (Sickness Impact Profile), social support (Social Support List, Interactions and Discrepancies).

Systemic factors (only at baseline): venous blood samples systemic high sensitivity C-reactive protein (hs-CRP), interleukin-6 (IL-6), tumornecrosisfactor-á (TNF-á), interleukin-1á

(IL-1á), interleukin-1â (IL-1â), interleukin-1-RA (IL-1-RA), interleukin-10 (IL-10), fibrinogen, leukocytes, cortisol, haemoglobin, glucose, thyroid function (TSH), renal function (creatinine), sodium, potassium, calcium, magnesium, vitamin B12, vitamin 25(OH)D3, liver function (aspartate-aminotransferase (ASAT) and alanine-aminotransferase (ALAT)), N-Terminal pro-Brain Natriuretic Peptide (NT-pro-BNP), blood sediment (BSE), antinuclear antibodies (ANA) and deoxyribonucleic acid (DNA).

Additional tests for patients from the Maastricht region: a resting cardiac echocardiography (n=200 – only at baseline), a resting electrocardiodiagram (n=200 – only at baseline), a polysomnography (n=50; n=25 with normal fatigue, n=25 with severe fatigue matched for age, gender, FEV1 and BMI – only at baseline), and retinal imaging to assess retinal microcirculation (n=200 – only at baseline).

Additional tests will be done when patients are admitted to the hospital. Non-elective hospitalizations due to an exacerbation of COPD may occur at any moment after the start of the study. Those which occur between baseline and 12 months will result in additional measurements. During one of the first days of the hospitalization fatigue measured with the CIS-Fatigue, the dyspnoea (mMRC), the impact of COPD on the health status (CAT), and symptoms of anxiety and depression (HADS) will be administered. Two weeks after discharge these measures will be repeated in the patients' home environment.

At last, at month 18 and 24 (6 months and 1 year after the completion of the study) the participants will be called to follow-up on their exacerbations, exacerbation-related hospitalizations and survival. In addition, they will be asked to fill out the CIS-Fatigue scale.

Study description

Background summary

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.

Study objective

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).

Study design

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.

Intervention

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

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other

Control: N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2018
Enrollment:	400
Type:	Anticipated

Ethics review

Positive opinion

Date:	08-01-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 53067
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

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

Study results

Summary results
N.a.