COPD monitoring

Published: 02-03-2021
Last updated: 08-04-2024

The purposes of this feasibility study are: • to evaluate the correlation between COPD-related dyspnea and the EMG of respiratory muscles when simulating daily activities, to assess the dyspnea symptom in a more objective (measurable) way; • to...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON56095

Source
ToetsingOnline

Brief title
COPD monitoring

Condition

- Respiratory disorders NEC

Synonym
COPD, dyspnea

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum
Source(s) of monetary or material Support: Medtronic

Intervention

Keyword: COPD, Dyspnea, EMG (of respiratory muscles), respiration

Outcome measures

Primary outcome

The primary objective and endpoint of the study is:

• To evaluate the EMG of respiratory muscles during various levels of dyspnea and exertion in COPD patients.

Secondary outcome

The secondary objectives of this study are:

• To characterize EMG, respiration rate, SpO2 and patient-reported health information (about dyspnea and other symptoms) before, during and after acute exacerbations of COPD;

• To characterize the respiration rate during various levels of dyspnea and exertion in COPD patients;

•To characterize the SpO2during various levels of dyspnea and exertion in COPD patients.

Secondary endpoints are:

• Change in EMG, respiration rate, SpO2 and patient-reported health information (Exact-PRO) before, during and after exacerbations of COPD.

• Correlation between respiration rate, as measured by the BioNomadix wearable data logger system, and Borg scale during exercise

• Correlation between SpO2 as measured by the WristOx2 3150 wearable pulse oximeter, and Borg scale during exercise

Study description

Background summary

Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities, usually caused by significant exposure to noxious particles or gases and influenced by host factors, including abnormal lung development (GOLD 2020 guidelines). COPD is a disabling respiratory illness that afflicts *10% of individuals over 40 years of age (O*Donnel et al., 2016), causing chronic morbidity and mortality throughout the world (Krahnke et al., 2015). The main causes of COPD are smoking, respiratory infections, air pollution, dust, and chemicals in poorly ventilated areas. According to the latest World Health Organization (WHO) estimates (https://www.who.int/respiratory/copd/en/, 2004), currently 64 million people have COPD, and 3 million people die yearly of COPD. WHO predicts that COPD will become the third leading cause of death worldwide by 2030.
The disease is characterized by gradual deterioration in lung function with multiple distressing symptoms like dyspnea and fatigue (Park et al., 2013). Dyspnea is referred to as the sensation of breathlessness, shortness of breath, or difficulty of breathing and it is often associated with limited physical activity, increased anxiety and depression, decreased health-related quality of life (HRQoL), and reduced survival (Anzueto et al., 2017). Scales and questionnaires are used in the current clinical practice to evaluate this symptom, that was defined as the *subjective experience of breathing discomfort that consists of qualitatively distinct sensations that vary in intensity* (Parshall et al., 2012). Dyspnea assessment, indeed, is achieved by questioning the patient about the onset, frequency and duration of the symptoms and its impact on daily activities. According to data from the Clinical Practice Research Datalink, 82% of patients with COPD had dyspnea of any grade, as assessed by the Medical Research Council (MRC) breathlessness scale (1-5), of whom 46% had moderate-to-severe dyspnea (MRC >=3). Moderate-to-severe dyspnea was also observed in 32% of patients with mild airflow obstruction, indicating that dyspnea is not limited to patients with more severe COPD (Mullerova et al. 2014). The Borg CR10 Scale, takes into account the patient*s perception. The scale starts with *Nothing at all" and ends with *Extremely strong* (Borg et al., 1982).
In COPD patients, dyspnea during exercise reflects an imbalance between the increased demand to breathe and the ability to meet that demand (Barros de Sà et al., 2017). A strong correlation between the intensity of dyspnea (measured

through the modified 10-point Borg scale) and the (relative) amplitude of the surface electromyography (EMG) of the respiratory muscles during exercise testing was found (Barros de Sà et al., 2017). To our knowledge, the correlation between dyspnea (BORG) scale and EMG has not been assessed during exercises that resemble daily activities more closely, such as a constant work rate test (CWRT), walking on a treadmill and/or cycling.
Another factor that has a major impact on COPD patients is the acute exacerbations (AECOPD), defined as an acute worsening of the respiratory symptoms (dyspnea, coughing and sputum) that results in additional therapy (Wilkinson et al., 2004; GOLD2020) and that typically lasts for several days. Because exacerbations strongly affect quality of life, disease progression and health care costs (Guarascio et al., 2013), it is important to enable early detection and prompt treatment, thereby reducing the risk of hospitalization, and improving quality-of-life. Exacerbations represent a high economic and social burden on the health care system (McGuire et al., 2001).
To identify the risk of early readmission among patients hospitalized due to an exacerbation of COPD and detect inpatient clinical deterioration, parasternal EMG can be helpful (Suh et al., 2015). Parasternal EMG has been shown to be a physiological biomarker of worsening dyspnea (Suh et al., 2015).
Patient-reported dyspnea associated with activities of daily living has also shown to be an important factor for predicting hospitalizations due to AECOPD (Abascal et al, 2015). Several studies have assessed the value of telemonitoring of symptoms and/or physiological parameters, of COPD patients. Some studies suggest that telemonitoring enables early detection of COPD exacerbations, but this has not been confirmed in large clinical trials (Sink 2018, Fernandez-Granero, 2014, Li 2020). Among the physiological parameters, breathing rate (at rest), as well as transcutaneous oxygen saturation (SpO2) and heart rate (both during effort situations), show promise in predicting exacerbations (Rubio 2017; Galvez-Barron 2019; Buekers 2018).

Study objective

The purposes of this feasibility study are:
• to evaluate the correlation between COPD-related dyspnea and the EMG of respiratory muscles when simulating daily activities, to assess the dyspnea symptom in a more objective (measurable) way;
• to characterize changes in EMG, respiration rate and SpO2 while simulating daily activities, associated with exacerbations of COPD.
• to characterize SpO2 and respiration rate when simulating daily activities;
The above-mentioned points serve together the aim of detecting exacerbations earlier and to provide better treatment, to improve patients* quality of life.

Study design

this is a prospective, non-randomized, single-arm, feasibility study.
Up to 31 subjects with a clinical diagnosis of COPD and referred for

rehabilitation at the rehabilitation center for respiratory pathologies (CIRO, The Netherlands) will be enrolled. The point of enrollment is the time when subjects sign and date the Informed Consent Form (ICF), once verified all the Inclusion/Exclusion (I/E) criteria. At that point, the subject is considered included in the study.
The I/E criteria of the subjects will be reviewed during a standard of care Pre-rehabilitation visit (not part of the study visits) performed by the attending physician. At the Pre-rehabilitation visit, the attending physician will ask eligible subjects if they are interested in participating in a clinical study and -if so- ask their permission to be put in contact with the Principal Investigator (PI) or his designee.

If they agree, the PI or his designee will deeply discuss the present study with the subjects and provide them the Subject Information Letter and Informed Consent at the end of the Pre-rehabilitation visit. Once the rehabilitation at the rehabilitation center has been planned by the attending physician and not earlier than 7 days after the pre-rehabilitation visit, the Investigator or his designee will contact the subject by phone to answer any further question the subject might have on the study. The admission visit will be scheduled after this phone call, to have ample time to reflect and decide whether or not to participate in the present study. At the admission visit, the Inclusion/Exclusion (I/E) criteria will be checked by the PI or his designee who will enroll eligible subjects by having them sign the Informed Consent Form (ICF). During the Admission visit, the PI or his designee will also retrospectively collect data, which have been previously recorded at the Pre-rehabilitation visit, as part of the site standard of care. At time of the Admission visit, once the informed consent process is completed, clinical data assessed at time of standard of care Pre-rehabilitation visit will be collected retrospectively for enrolled subjects. The Admission visit will take place at the beginning of the rehabilitation program, then 8 Follow-up visits (once per week) will be planned during their rehabilitation program.
Additional Exacerbation-triggered visit(s) may be performed during acute exacerbations, diagnosed by a physician in accordance with the GOLD guidelines, occurring while subjects are at the rehabilitation center.
Finally, before Study Exit, a Pre-discharge visit will be scheduled at the end of subject*s rehabilitation program (refer to section 9 for additional details on the procedures).
Physiological parameters will be collected during the Admission, Follow-Up and Exacerbation-triggered visits and Pre-Discharge visit.
Data analyses are expected to be completed for internal review approximately 6 months after the last subject*s Pre-discharge visit will occur.

Intervention

Please see study design above.

Study burden and risks

The participants will perform an exercise (cycle) test during the admission visit, during which various physiological parameters (such as EMG; complete list provided in the CIP) will be measured.
During 8 follow-up visits, possible exacerbation-triggered visits and 1 pre-discharge visit, physiological parameters (EMG, oxygen saturation and respiration rate) will be measured while the subjects perform their regular exercises / tests.
Wearable, non-invasive devices will be used for the measurement and data collection. Wearing the measurement devices, i.e. the electrodes (for the EMG of the respiratory muscles) and the chest strap (for the respiration rate) during the study visits may cause mild skin irritation.
Subjects will be also provided with a paper diary, which they will be asked to complete daily before going to sleep, during their stay at Ciro (from the day of the admission until the day before the study exit).
The potential risks associated with the study were identified, assessed, evaluated and effectively controlled. Medtronic has reduced the residual risk to as low as possible prior to starting the clinical study. Any potential risks associated with this study are further minimized by selecting a qualified investigator. Moreover, the investigator and respective study site personnel will be trained on Clinical Investigation Plan. Therefore, it was concluded that the overall benefits outweigh the risks.

Contacts

Public
Selecteer

Endepolsdomein 5
Maastricht 6229 GW
NL
Scientific
Selecteer

Endepolsdomein 5
Maastricht 6229 GW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

1.Subject must have a clinical diagnosis of COPD
2. mMRC (Modified Medical Research Council) Dyspnea Scale Score > 1
3. Subject must be indicated for regular inpatient/outpatient pulmonary rehabilitation at CIRO
4. Subject must be willing to provide Informed Consent for their participation in the study
5. Subject must be >=18 years of age

Exclusion criteria

1. Subjects who are unable/unwilling to voluntarily participate in the study
2.Subjects who cannot read/write
3. Subject has congenital heart disease
4.Subject has unstable coronary artery disease
5.Subject has an active implanted cardiac device (i.e. IPG, ICD)
6.Subject has heart failure NYHA 4
7.Subject presents any concomitant condition which in the opinion of the investigator would not allow a safe participation in the study
8.Subject is legally incompetent
9.Subject is pregnant or has suspect to be pregnant
10.Subject is enrolled in a concurrent study that may confound the results of this study without documented pre-approval from Medtronic study manager
11. BORG scale assessment is evaluated as unreliable due to patient*s cognitive condition

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	08-02-2022
Enrollment:	31
Type:	Actual

Medical products/devices used

Generic name:	WristOx2 3150 wearable pulse oximeter (Nonin Medical;Inc)
Registration:	Yes - CE intended use

Ethics review

Approved WMO

Date:	02-03-2021
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	04-07-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	30-12-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL72724.068.20