Continuous monitoring of ventilation with the Hexoskin smart shirt to detect dynamic hyperinflation in COPD patients

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

Summary

ID

NL-OMON43533

Source
ToetsingOnline

Brief title
CHOPIN

Condition

- Respiratory disorders NEC

Synonym
Dynamic hyperinflation (COPD)

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: Geld van universiteit aan ziekenhuis

Intervention

Keyword: COPD, Dynamic hyperinflation, Hexoskin, Wearables

Outcome measures

Primary outcome

The main endpoint in this study is the Pearson correlation coefficient between the Hexoskin smart shirt and the standard devices to detect and quantify dynamic hyperinflation

Secondary outcome

Furthermore the degree of dynamic hyperinflation that is detected with the Hexoskin smart shirt expressed either in milliliters or in arbitrary units is determined. Other outcome parameters are the sensitivity and specificity to detect dynamic hyperinflation and the usability of the shirt. A possible correlation between Borg dyspnea scores and the occurence of dynamic hyperinflation will be assessed as well.

Study description

Background summary

COPD is a disease with a high prevalence and high morbidity, mortality and health care costs. One of the main problems in COPD is unexplained dyspnea, especially during exercise. In the past years research has focused on unravelling the process of dynamic hyperinflation, seen as the main cause of dyspnea at exercise. Research has shown that reduction in dynamic hyperinflation (DH), can diminish the burden of disease in COPD. However, until now, no ambulant and continuous monitoring tool is available to detect and quantify the degree of DH in COPD. In this study the Hexoskin smart shirt, capable of measuring several cardiopulmonary vital parameters is assessed for its usability in COPD diagnostics and treatment.

Study objective

The main objective of this study is to assess the ability of a wearable measurement system, the Hexoskin smart shirt, to detect and quantify dynamic hyperinflation. Secondary objectives are to determine the optimal measurement procedure and to assess the accuracy, usability and convenience of the smart shirt.

Study design

The study will be carried out in two phases. Phase 1 is a cross-sectional pilot study with fifteen healthy volunteers. Phase 2 is a prospective comparison study between fifteen COPD patients (with a high likelihood of experiencing dynamic hyperinflation) and fifteen non-COPD (*healthy*) patients and is executed in clinical practice.

Intervention

The Hexoskin smart shirt will be applied during several pulmonary function tests: a standard spirometry procedure, a metronome-paced tachypnea test and an exercise test. The standard pulmonary function equipment based on flow and pressure differences is used for comparison of the respiratory parameters such as tidal breathing and breathing frequency.

Study burden and risks

Subjects in this study will participate during a single visit to the pulmonary function department. In phase one participation to the tests is estimated to take about thirty minutes. In phase two the time of testing is estimated to be fifteen minutes on top of the regular time of the, already planned, lung function tests. No benefits are related to participating in the study. The risks of participating in this study are negligible.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy subjects:
- Adult, volunteers;Patient group:
- Patients with COPD (GOLD I-IV) that receive planned pulmonary function testing including spirometry and a form of exercise testing (6 minute walk test and/or cardiopulmonary exercise test (CPET)).
- Patients with the clinical suspicion of hyperinflation based on the expert*s opinion. For example a barrel -shaped thorax or Hoover sign during physical examination, or a known increased resting volume (RV) present in spirometry data.;Control group:
- Patients who do not have a clinically defined COPD phenotype and do not have an outflow obstruction (No decrease in the Tiffenau index).
- Patients that receive the same planned pulmonary function tests as the patient group.

Exclusion criteria

- An exacerbation of COPD with hospital admission in four weeks prior to inclusiondate.
- Other associated disease (heart, neurological, rheumatic, or orthopedic).
- Physical impairments causing any disability to perform a physical task
- Inability to read, understand or speak Dutch
- Subjects who do not fit into one of the available sensor shirts
- Subjects with a pacemaker / Implantable cardioverter-defibrillator (ICD) device

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	25-02-2016
Enrollment:	60
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2016
Application type:	First submission
Review commission:	METC Twente (Enschede)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

ID: 21984
Source: Nationaal Trial Register

Title:

In other registers

Register	ID
CCMO	NL56190.044.15
OMON	NL-OMON21984