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

No registrations found.

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

Summary

ID

NL-OMON21984

Source
Nationaal Trial Register

Brief title
CHOPIN

Health condition

dynamic hyperinflation; COPD; Hexoskin; dyspnea ; dyspneu;metronome - paced tachypnea ; hyperinflatie

Sponsors and support

Primary sponsor: Medisch Spectrum Twente, Enschede
Source(s) of monetary or material Support: University of Twente, Enschede (free of charge)

Intervention

Outcome measures

Primary outcome

Correlation between the lung function equipment and the Hexoskin smart shirt for the

detection of dynamic hyperinflation in patients with COPD.

Secondary outcome

The degree of dynamic hyperinflation

- Cohen's kappa to assess the level of agreement between the two used methods.

- Linear regression to describe the correlation

- Sensitivity and specificity in the detection of dynamic hyperinflation under the assumption that lung function equipment serves as gold standard.

- Bland Altman analyssis

- User experience of the smart shirt

Study description

Background summary

In this study the Hexoskin smart shirt is tested for its applicability to detect and quantify dynamic hyperinflation in COPD patients. First a group of healthy volunteers will be measured, followed by a group of patients to test the accuracy of the shirt for the detection of dynamic hyperinflation.

Study objective

The hypothesis is that the Hexoskin smart shirt is able to detect dynamic hyperinflation in COPD patients, based on the respiratory inductance plethysmography technique incorporated in the shirt.

Study design

A single visit to the hospital for participation in the study.

Intervention

No intervention, just monitoring of the vital parameters with the Hexoskin smart shirt.

Contacts

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Eligibility criteria

Inclusion criteria

Phase 1:

- Healthy adult control subjects

Phase 2:

- Patients with COPD GOLD II-IV

- Patients with a high likelihood of experiencing dynamic hyperinflation, based on the expert's opinion and clinical parameters such as residual volume and a barrel shaped thorax.

- Patients that receive planned lung function tests, including spirometry and exercise testing.

- Patients with pulmonary problems, other than COPD, are incorporated in the control group of phase 2.

Exclusion criteria

- Inability to fit the available shirts

- Physical impairments preventing the execution of a physical task

- inability to read, speak or understand Dutch

- Subjects with a pacemaker or ICD device

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-03-2016
Enrollment:	45
Type:	Anticipated

Ethics review

Positive opinion

Date:	25-01-2016
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

ID: 43533
Bron: ToetsingOnline

Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL5485
NTR-old	NTR5620
CCMO	NL56190.044.15
OMON	NL-OMON43533

Study results