# 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

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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**

#### **Public**

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#### **Scientific**

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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
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- 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

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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**