How to exactly measure lung volumes in healthy subjects and COPD patients, non-invasively?

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The primary objective is to investigate the validity of the volumes measured by the Hexoskin shirt relative to a (mobile) spirometer in healthy subjects and in COPD patients. Secondary objective are to determine reliability of the Hexoskin shirt...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON50486

Source
ToetsingOnline

Brief title
The Hexoskin Study

Condition

- Other condition
- Lower respiratory tract disorders (excl obstruction and infection)

Synonym
chronic obstructive pulmonary disease, COPD

Health condition

gezonde luchtwegen

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum
Source(s) of monetary or material Support: Chiesi Farmaceutici,EFRO

Intervention

Keyword: dynamic hyperinflation, lung volumes, respiratory inductance plethysmography, wearable

Outcome measures

Primary outcome

The main study parameter will answer the main objective, can the Hexoskin shirt measure volume relative to the gold standard (spirometer / mobile spirometer), valide. For measurement A and B (position and activity measurements) the mobile spirometer (Oxycon Mobile) will be the gold standard, per subject more tidal volumes are calculated and will be compared between both methods. The Bland-Altman is calculated overall (measurement A and B together) and per task/activity. For measurement C and D (lung function tests), a spirometer or bodybox is the gold standard, per subject one value of IC or EELV, FEV1, VC and FVC are used for the Bland-Altman plots. In both parts of the study, a 95% CI below 15% difference will indicate that the Hexoskin shirt can validly measure volumes.

Secondary outcome

Secondary parameters are intra class correlation coefficient for reliability, mixed modesl repeated measurement analyse to find differences in calibration parameters for the various tasks, systematic error by means of the bias, percentage error of the volumes, correlation between demographic parameters and

percentage error, and the experience with the Hexoskin shirt.

Study description

Background summary

COPD patients have problems with their breathing, and develop DH. DH is correlated to the dyspnea sensation, as experienced by the subjects. The gold standard to measure DH, is with use of a spirometer and by performing a breathing manoevre (inspiratory capacity manoevre) before and after exercise. This gold standard has a number of dis-advantages: (1) active participation of a subject is necessary, (2) because of the exercise, patients are fatigued and this can have an influence on the measured inspirotory capacity, (3) DH can not be assessed continuously, (4) DH can not be assessed in the home situation. A promising technique, which is able to measure long volumes and possibly DH, is respiratory inductance plethysmography (RIP). These sensors, relate a change in circumference of the thorax and abdomen to the inspiratory or expiratory volume. Before this technique can be used in clinical practice/ home situation, the measured long volumes have to be compared to a gold standard and have to be repeatable. The RIP sensors are placed in a shirt, the Hexoskin shirt.

Study objective

The primary objective is to investigate the validity of the volumes measured by the Hexoskin shirt relative to a (mobile) spirometer in healthy subjects and in COPD patients. Secondary objective are to determine reliability of the Hexoskin shirt measurement, the correlation with spirometer, effects of position and activity, reliability of the Hexoskin shirt to measure DH and to investigate the subjects experience with the Hexoskin shirt.

Study design

The study is divided into two parts. The first part is a pilot study, the second part is a cross-sectional study. If part 1 shows poor agreement of volumes measured with the Hexoskin shirt and (mobile) spirometer (gold standard), the study will be terminated prematurely.

Study burden and risks

No potential risks of wearing the shirt are known and expected. There are no potential risks mentioned or found in studies involving The Hexoskin shirt. Subjects in both groups do not benefit from participation. If unexpected findings exist, in the standard lung function examinations, the subject and his or her general practitioner/ treating specialist will be informed on these

results.

Contacts

Public
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525 GA
NL
Scientific
Radboud Universitair Medisch Centrum

Geert Grooteplein 10
Nijmegen 6525 GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Healthy subjects:
- Healthy, adult subjects between the age of 18 - 80 years.
- Normal lung function (FEV1 > 80%)
- Written informed consent prior to participation.
COPD patients:
- Patients with stable COPD. FEV1 < 80% predicted (GOLD stage II-IV).
- Written informed consent prior to participation.

Exclusion criteria

- Exacerbation within 1 month before inclusion
- Physical impairment causing any disability to perform physical tests
- Subjects who do not fit one of the available shirts
- Subjects with a pacemaker/ ICD device
- Inability to read and/or understand the Dutch language

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):	25-09-2018
Enrollment:	60
Type:	Actual

Medical products/devices used

Generic name:	Hexoskin shirt
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	03-05-2018
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

Approved WMO Date:	03-02-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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: 22284
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL65299.044.18