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

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the hexoskin shirt can adequately measure lung volumes, compared to the gold standard

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON22284

Bron
Nationaal Trial Register

Verkorte titel
The Hexoskin Study

Aandoening

healthy and COPD

Ondersteuning

Primaire sponsor: Radboudumc
Overige ondersteuning: Efro, Chiesi

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The primary study parameter will answer the main objective, can the Hexoskin shirt accurately measure volume relative to the gold standard (spirometer or Oxycon Mobile). This

analysis is performed in healthy subjects and later on in COPD patients. The Bland-Altman plot will be plotted as a percentage instead of a absolute difference. And is calculated with: ((volumes Method A – volumes Method B) / mean volumes of both methods x 100%), in which Method A is the Hexoskin shirt and Method B spirometer or Oxycon Mobile

Toelichting onderzoek

Achtergrond van het onderzoek

In this study a non-invasive and continuous monitoring wearable, the Hexoskin shirt (with respiratory inductance plethysmography sensors), will be tested on its reproducibility, repeatability and reliability to measure lung volumes and dynamic hyperinflation (DH). The primary objective is to investigate the accuracy of the volumes measured by the Hexoskin shirt relative to a (mobile) spirometer in healthy subjects and in patients with chronic obstructive pulmonary disease. Secondary objective are to determine repeatability 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.

Doel van het onderzoek

the hexoskin shirt can adequately measure lung volumes, compared to the gold standard

Onderzoeksopzet

-

Onderzoeksproduct en/of interventie

N.A.

Contactpersonen

Publiek

Nijmeegsebaan 31
D.C. Mannée
Groesbeek 6561 KE
The Netherlands
+31 (0) 6 15 43 33 75

Wetenschappelijk

Nijmeegsebaan 31
D.C. Mannée
Groesbeek 6561 KE
The Netherlands
+31 (0) 6 15 43 33 75

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

In part 1, thirty healthy subject between 18-80 years are included, after signing informed consent. All subjects have a normal lung function (forced expiratory volume in 1 second (FEV1) > 80%).

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

In part 2, thirty COPD patients are included. All subjects have a lung function with FEV1 < 80%, corresponding to GOLD stage II-IV. Exclusion criteria, for both parts of the study, are physical impairment to perform physical tests, not fitting an available shirt, presence of a pacemaker or implantable cardioverter defibrillator, inability to read/understand Dutch language. And for COPD patients, an exacerbation within 1 month before inclusion is a exclusion criteria.

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	25-09-2018
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	05-04-2018
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 50486
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL6934
NTR-old	NTR7130
CCMO	NL65299.044.18
OMON	NL-OMON50486

Resultaten

Samenvatting resultaten

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