Effects of body composition on respiration detection

Published: 30-03-2018
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Primary objective:- Bepalen of de nauwkeurigheid van de ROBIN geschikt is voor ademhalingsmonitoring in vergelijking met spirometrie.Secondary objective- Bepalen van het effect van veranderingen in de lichaamssamenstelling op de amplitude van de...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON47668

Source
ToetsingOnline

Brief title
Body composition

Condition

- Other condition

Synonym
sleep apnea

Health condition

astma, COPD, slaapapneu

Research involving
Human

Sponsors and support

Primary sponsor: Stichting IMEC Nederland
Source(s) of monetary or material Support: Stichting Imec Nederland

Intervention

Keyword: Bioimpedance, Body composition, Heart rate, Respiration, Sleep apnea

Outcome measures

Primary outcome

- Mean difference in measured respiratory rate/volume between ROBIN and spirometer

Secondary outcome

- Correlation coefficient between respiratory rate/volume between from ROBIN and spirometer

- Correlation coefficient between changes in body composition and impedance amplitude (and derived parameters)

- Correlation coefficient between changes activity profiles and errors in calculated respiratory rate and volume

- Difference in error between electrode configuration 1 and 2 for estimations of respiratory rate of respiratory volume (see section 8.3 in protocol)

Study description

Background summary

Recently, Stichting Imec Nederland developed the ROBIN, an instrument for measuring respiration. The ROBIN offers possibilities to continuously and reliably measure respiration. Breathing is measured by determining the impedance of the upper body.

The impedance of the upper body, and also the accuracy of the ROBIN, are mainly determined by the composition of the upper body. The composition of the upper body depends on ratios in muscle, water, fat, air and bone.

The ROBIN can measure both breathing and changes in body composition. This combination would allow the ROBIN to indicate when a measurement is no longer reliable. Researchers expect that measurement of impedance alone will not be sufficient and therefore, in addition to impedance, additional contextual information such as activity level is also taken into consideration.

In the past, ROBIN has already been tested on healthy subjects. The results were promising, but under normal circumstances body composition and impedance do not not change. Patients undergoing bariatric surgery will gradually experience significant changes in body composition. This scenario offers (according to the researchers) the biggest change that both sensor module and algorithms will ever encounter.

The aim of this study is to validate whether chest impedance(as measured with the ROBIN device) is a suitable method for continuous long-term respiration monitoring.

Steps are also taken towards the identification of parameters needed to develop quality indicators and self-learning algorithms. This can ultimately lead to more suitable methods for measuring respiration accurately.

Study objective

Primary objective:
- Bepalen of de nauwkeurigheid van de ROBIN geschikt is voor ademhalingsmonitoring in vergelijking met spirometrie.

Secondary objective
- Bepalen van het effect van veranderingen in de lichaamssamenstelling op de amplitude van de impedantiesignalen.
- Onderzoek of veranderingen in activiteitenprofielen zijn gecorreleerd aan fouten in de door ROBIN berekende ademhalingsparameters.

Study design

Interventional:

The data required for this study will be gathered from 20 patients undergoing bariatric surgery. In total, the subjects are measured at five different times (0, 3, 6, 9 and 12 months after the procedure).
Each session is exactly the same and takes about 30 minutes:

- Weight and body composition are measured with a scale
- Body composition is measured by the ROBIN.
- Several breathing exercises:
    - Free breathing
    - Breath hold after exhalation
    - Chest breathing
    - Superficial breathing
    - Abdominal breathing
    - Slow breathing
    - Fast breathing

A spirometer (breathing meter) is also used during the exercises.

After the first measurement, the test subject will receive an activity monitor (FitBit), a wristband that measures how much test subjects move daily. Test subjects are asked to wear the FitBit as often as possible during the study. If not possible, the subject is requested to use the FitBit at least 2 weeks after each measurement.

Intervention

- Breathing exercises using the ROBIN and spirometer
- Wearing an activity monitor (FitBit)

See section study design

Study burden and risks

No significant risks or immediate benefits are expected for the participants.

In the event that ROBIN should go broke, there is a chance that a small power surge is experienced by the participant, so far this has not happened yet. The ROBIN supply voltage is 4.2 V. which is considered safe for contact with the skin. Furthermore, impedance measurements are carried out under the supervision of the research assistant.

The additional load for the participants consist of: the time it takes to carry out the measurements (approx. 30 min per session), removal of ECG electrodes and wearing the activity monitor

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

- Patients undergoing a stomach reduction
- Age > 18
- Informed consent
- BMI > 28

Exclusion criteria

- Known allergy to adhesive Ag/AgCl electrodes
- Subjects who are pregnant or likely to become pregnant
- Subjects with implantable devices, such as pacemaker, ICD or implanted infusion pump
- Subjects using medication with with phototoxic side effects.
- Tetracylines
- Doxycycline
- Phenothiazines
- Dacarbazine
- Ketoprofen
- Lomefloxacin

This in order to exclude the possibility of local skin irritation from prolonged irradiation by LED-light (from the activity monitor).
- Patients that do not want to be informed in case of incidental findings.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	13-09-2018
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Date:	30-03-2018
Application type:	First submission
Review commission:	METC Maxima Medisch Centrum (Veldhoven)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL61577.015.17