Assessment of respiratory effort in healthy volunteers: esophageal pressure versus noninvasive monitoring techniques.

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

Summary

ID

NL-OMON48440

Source
ToetsingOnline

Brief title
respiratory effort

Condition

- Other condition

Synonym
obstructive sleep apnea, sleep apnea

Health condition

slaapstoornissen, obstructief slaapapneu

Research involving

Human

Sponsors and support

Primary sponsor: Kempenhaeghe
Source(s) of monetary or material Support: de onderzoeker wordt door Kempenhaeghe betaald

Intervention

Keyword: esophageal pressure, noninvasive techniques, respiratory effort

Outcome measures

Primary outcome

Relationships between noninvasive measurement techniques to measure respiratory

effort and esophageal pressure measurement with varying respiratory resistance.

The relationship between respiratory effort and snoring intensity.

Secondary outcome

Not applicable.

Study description

Background summary

Esophageal pressure measurement is considered the gold standard technique for measuring respiratory effort during polysomnography in the context of obstructive sleep apnea (OSA) research. However, in clinical practice this technique is not often used because the insertion of an esophageal pressure catheter is time-consuming, requires competent staff, the catheter is not always tolerated or can even disrupt the patient's sleep. There are several promising non-invasive techniques on the market to measure respiratory effort. To date, however, little research has been done on how these non-invasive techniques relate to esophageal pressure measurement.

Study objective

The aim of the study is twofold: 1) to determine the relationship between invasive (gold standard) and non-invasive techniques for measuring respiratory

effort. 2) by means of gradations of snoring intensity, the relation between respiratory effort and snoring intensity is examined. Both research questions are examined in an experimental study in healthy volunteers.

Study design

Through advertisements, a call is made to healthy volunteers to participate in this study. Volunteers who meet the inclusion criteria, different measuring instruments will be applied: esophageal pressure catheter, thoracic abdominal bands, diaphragm EMG, EMG of the m. Sternocleidomastoid, suprasternal pressure measurement, pulse oximetry, ECG and transcutaneous CO2 measurement. The examination room is equipped with a microphone for snoring analysis that hangs one meter above the test subject. During the measurement itself, the test subject receives a in which the resistance can be adjusted.

Intervention

In the first phase of the study, volunteers are asked to breathe through a mouthpiece and the resistance will gradually be increased by 10 mmHg per session to a maximum of 60 mmHg. In the second phase of the study, the volunteer is asked to snore with three different intensities, ie soft, harder and as hard as possible.

Study burden and risks

There is no direct benefit for the volunteers to participate in this study. The participants have to come only once to the Centre of Sleep Medicine Kempenhaeghe in Heeze . The full duration of the examination, application of the equipment plus measurement, will take approximately one hour. The potentially most stressful technique during this study is the esophageal pressure measurement. In some candidate subjects insertion of the esophageal catheter may not be possible due to nasal obstruction, so that participation in the study is not achievable. Although esophageal pressure measurement is a standard clinical technique , in some volunteers the catheter could be experienced as uncomfortable or even painful, so they might choose to stop the study. Possible complications of a esophageal catheter are irritation of the mucous membrane and nose bleeding. The other techniques are not invasive and the risk of damage is minimal.

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

healthy volunteers
adults

Exclusion criteria

pulmonary disease
heart disease
neuromuscular disease

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):	20-05-2019
Enrollment:	10
Type:	Actual

Ethics review

Approved WMO

Date:	29-03-2019
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	NL68688.015.19