

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

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<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	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 CO<sub>2</sub> 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**

### **Public**

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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**

CCMO

**ID**

NL68688.015.19