THE VALIDITY OF THE AEONOSE IN DISCRIMINATING DYSPNEA RESULTING FROM HEART FAILURE OR FROM PULMONARY ORIGIN

No registrations found.

Ethical review	Not applicable
Status	Other
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON25949

Source
NTR

Brief title
AEONOSE HF LF

Health condition

heart failure (NYHA class II-IV)
COPD GOLD class II-IV
Enose

Sponsors and support

Primary sponsor: Diaconessenhuis Meppel
Source(s) of monetary or material Support: The Enose company

Intervention

Outcome measures

Primary outcome

The ability of the Aeonose to discriminate between patients with heart failure (NYHA class II-IV) versus COPD GOLD class II-IV

Secondary outcome

- Time involved in obtaining Aeonose read-out

- Technical or patient related problems obtaining a read-out from the Aeonose.

- Adverse effects of using the Aeonose

Study description

Study objective

The Aeonose is capable to correctly distinguish patients with dyspnea resulting from heart failure from patients with dyspnea caused by lung failure.

Study design

single measurement

Intervention

All participants will be asked to breath 5 minutes through the sampling setup that consists of a non-rebreathing T-valve with an active carbon filter attached to the inlet. During sampling, a nose clamp will be placed on the nose of the participant to avoid entry of non-filtered air. The first 2 minutes are used to flush the environmental influences from the lungs after which the exhaled air is measured during 3 minutes followed by a recovery period of 4 minutes. Finally, the build-in absorber is cleared during 1 minute (20 sec heating followed by 40 sec cool-down) to release the attached volatiles followed by the final measurement period of 5 minutes under influence of the clean reference air.

Contacts

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Eligibility criteria

Inclusion criteria

• Signed Informed consent

• A diagnosis of either heart failure NYHA class II-IV or COPD GOLD severity of obstruction II-IV.

• age > 40years

Exclusion criteria

• Artificial cardiac pacemaker

• Atrial fibrillation or atrial flutter

• Acute medical events in the 6 weeks prior to inclusion (cardiac, pulmonary or otherwise if requiring an intervention)

• Patients with cancer

• Tracheostoma

• Inability to understand the patient information

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Other
Start date (anticipated):	01-10-2015
Enrollment:	450
Type:	Unknown

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL5281
NTR-old	NTR5388
Other	METC Zwolle : 15.07121

Study results