NAPELS: Breathiomics in acute pulmonary embolism

Published: 03-04-2009
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To assess the accuracy of the electronic nose in the diagnosis of pulmonary embolism.

Ethical review	Approved WMO
Status	Pending
Health condition type	Embolism and thrombosis
Study type	Observational non invasive

Summary

ID

NL-OMON33696

Source
ToetsingOnline

Brief title
NAPELS Studie

Condition

- Embolism and thrombosis

Synonym
pulmonary embolism, venous thromboembolism

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Breathiomics, Diagnosis, Pulmonary embolism

Outcome measures

Primary outcome

the smell-print provided by the electronic nose.

Secondary outcome

the negative and positive predictive values for the diagnosis of pulmonary

embolism.

Study description

Background summary

The differential diagnosis of acute pulmonary thromboembolism remains extensive and specialized diagnostic procedures are needed to confirm or exclude diagnosis. Recently, *omics* techniques became available, providing possibilities for analyzing the overall molecular characteristics of various biological samples by a single measurement. The electronic nose is a handheld device including on-board pattern recognition analysis software, providing the potential option of *on the spot* diagnosis of acute PE.

Study objective

To assess the accuracy of the electronic nose in the diagnosis of pulmonary embolism.

Study design

prospective cohort study

Study burden and risks

Patients will take the electronic nose test, which includes breathing normally through a mouthpiece for 5 minutes and then exhaling a vital capacity volume into a Tedlar bag connected to an expiratory port.
The analysis of the exhaled breathing volume carries no risks for the patients.

Contacts

Public
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland
Scientific
Academisch Medisch Centrum

Meibergdreef 9
1105 AZ Amsterdam
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients with clinically suspected pulmonary embolism

Exclusion criteria

Age < 18 years
LMWH or unfractionated heparin 24 hrs or more prior to eligibility assessment
vitamin K antagonists (coumarin derivates)
inability to perform the electronis nose test

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2009
Enrollment:	75
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL26237.018.08