Performance of the Aeonose[™] as a diagnostic tool to detect lung cancer: an external validation study

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20226

Source Nationaal Trial Register

Health condition

- presence or absence of lung cancer

Sponsors and support

Primary sponsor: Medisch Spectrum Twente Enschede Source(s) of monetary or material Support: The eNose Company, Zutphen

Intervention

Outcome measures

Primary outcome

the comparison of outcomes obtained from the Aeonose^m (21) with the outcomes obtained from the gold standard, which is histopathology. The outcomes will be presented as sensitivity, specificity, positive predictive value, negative predictive value and the AUC for the Aeonose^m as a diagnostic test to predict the probability of lung cancer.

Secondary outcome

Secondary study parameters are smoking status including amount of pack years, comorbidities, medication use, age and sex to describe the study population. In case of presence of lung cancer, clinical parameters such as tumour type and TNM stadium are noted.

Study description

Background summary

Worldwide there is an increasing interest to screen for lung cancer to detect this disease in an earlier and probably curable stage. Now would be the perfect time to develop an instrument with additional value to the current diagnostic path of lung cancer and the recently in Northern America (and almost in Europe) implemented low-dose CT scan as screening instrument for high-risk populations. Low-dose CT scanning results in over 95% false positive results and is therefore not efficient enough as a screening tool since it involves many invasive bronchoscopies with subsequently risk of complications and high costs. To increase the efficiency of lung cancer screening, this study evaluates the 'smell' of exhaled breath as a biomarker for the presence of lung cancer. Volatile organic compounds (VOC's) in exhaled breath are a result of metabolic changes due to tumour growth and the host's immune response. Electronic noses can recognize and classify these VOC's in terms of presence or absence of a disease. The Aeonose[™] from the Enose Company in Zutphen is trained to recognize specific alterations in breath prints of VOC's related to lung cancer, due to a prior Dutch multi-centre study coordinated by researchers from MST Enschede. 350 subjects were included of which approximately half were diagnosed with non-small cell lung cancer and half were healthy (proven negative or healthy volunteer). The study showed promising results in terms of diagnostic performance. Therefore, the aim of this study is to serve as a prospective, multi-centre validation study in an independent and larger study population.

Study objective

Primary Objective: To investigate the diagnostic performance of the Aeonose[™] to distinguish breath of subjects suspected for lung cancer who are truly diagnosed with lung cancer from subjects suspected for lung cancer in which this diagnosis is rejected with histopathology, by means of pattern recognition. The obtained patterns will also be compared with breath of healthy subjects who are considered healthy.

Study design

Lung cancer: yes or no. 1 measurement

Type of lung cancer: NSCLC or SCLC. 1 measurement

Stadium of lung cancer: TNM classification and staging. 1 measurement.

Intervention

Measurement of exhaled breath with an electronic nose.

Contacts

Public Deurningerstraat 54

Sharina Kort Enschede 7514 BJ The Netherlands 0031651421840 **Scientific** Deurningerstraat 54

Sharina Kort Enschede 7514 BJ The Netherlands 0031651421840

Eligibility criteria

Inclusion criteria

To be eligible as a patient to participate in this study, subjects need to match the following inclusion criteria:

- Referred for a CT scan and/or a histological biopsy due to suspicion for lung cancer.
- Age above 18 years.

Eligible healthy subjects need to meet the following criterion:

• Age above 50 years.

Exclusion criteria

Potential subjects will be excluded from participation in this study when meeting the following criterion:

• Known to have an active malignancy.

Study design

Design

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

Recruitment

NL	
Recruitment status:	Recruiting
Start date (anticipated):	22-05-2018
Enrollment:	800
Туре:	Anticipated

Ethics review

Positive opinion	
Date:	24-05-2018
Application type:	First submission

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

4 - Performance of the Aeonose[™] as a diagnostic tool to detect lung cancer: an ext ... 15-06-2025

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

No registrations found.

In other registers

Register	ID
NTR-new	NL7025
NTR-old	NTR7230
Other	: K18-18

Study results

Summary results

Kort S, Brusse-Keizer M, Gerritsen JW, Van Der Palen J. Data analysis of electronic nose technology in lung cancer: Generating prediction models by means of Aethena. J Breath Res [Internet]. 2017;11(2):26006.