Exhaled Breath profiling by an Electronic Nose in the Diagnosis of Pulmonary Sarcoidose

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Ethical review	Approved WMO
Status	Pending
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON35021

Source
ToetsingOnline

Brief title
eNose and Pulmonary Sarcoidosis

Condition

- Autoimmune disorders
- Respiratory disorders NEC

Synonym
Lung sarcoidosis

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Electronic Nose, Sarcoidosis

Outcome measures

Primary outcome

Smellprint of sarcoidosis patients versus controls.

Smellprint of patients with different radiological stages.

Secondary outcome

Hypothesize that an electronic nose can discriminate between different stages

of pulmonary sarcoidosis (sub-phenotyping)

Finally we aim to characterize VOCs in samples detected by the electronic nose

by gas-chromatography and mass-spectrometry

Study description

Background summary

Sarcoidosis is a systemic granulomatous disease of unknown cause that affects the lungs in over 90% of cases. On an epidemiological basis there is an association between the radiological stages I-IV and the prognosis of the lung involvement in terms of spontaneous resolution or persistent disease. However, there is a considerable variability in the prognosis of individual patients within these radiological phenotypes. There is no straightforward way to assess disease activity and severity, so that predicting the course and prognosis in individual cases is difficult. Decisions on whether or not to start treatment often have to be taken on arbitrary grounds.
During the last few years the analysis of exhaled breath has been proposed as a novel diagnostic tool for patients with a variety of lung diseases, including those with chronic inflammation ENoses represent an innovative method of sampling of volatile organic compounds (VOCs). They principally follow an empirical approach, allowing the distinction of *smell-prints* obtained from various gaseous sources by pattern recognition, providing discrimination of gas mixtures irrespective of the individual molecular components. We have validated this method and observed adequate discrimination between subjects with and without asthma and patients with asthma and COPD.

We hypothesize that an electronic nose can discriminate between the exhaled breath of patients with established pulmonary sarcoidosis from healthy controls. In addition, we hypothesize that an electronic nose can discriminate between different stages of pulmonary sarcoidosis (sub-phenotyping). Finally we aim to characterize the VOCs in samples detected by the electronic nose by gas-chromatography and mass-spectrometry.

Study objective

We hypothesize that an electronic nose can discriminate between the exhaled breath of patients with established pulmonary sarcoidosis from healthy controls
Secondly, we hypothesize that an electronic nose can discriminate between different stages of pulmonary sarcoidosis (sub-phenotyping)
Finally we aim to characterize VOCs in samples detected by the electronic nose by gas-chromatography and mass-spectrometry

Study design

A case-control cross sectional study will be performed with a total number of 120 subjects. 60 patients and 60 controls.

Study burden and risks

Minimal burden, no risks.

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

* Adult patients, between 18-70 years old, with a confirmed diagnosis of sarcoidosis. (Diagnosis of sarcoidosis according to the generally accepted consensus criteria.)
* Treatment naïve patients. A low dose oral prednisolone (< 10 mg daily) will be allowed.

Exclusion criteria

* Patients with underlying conditions with an established effect on the exhaled VOCs.
* Any other respiratory disease except sarcoidosis and/or any systemic diseases.
* Respiratory tract infections requiring antibiotics and/or oral steroids in the 4 weeks prior to the study will be excluded.
* Current and ex tobacco Smoking. (However, patients with a smoking history of < 1 packyear and no smoking during the past 10 years can be included).
* Prior diagnosis of malignancies

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2010
Enrollment:	120
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	NL31952.018.10