Volatile organic compounds in breath as marker of asthma and COPD: studies on methodologic aspects

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Study 1.Primary Objective: To investigate whether a portable electronic nose system (Cyranose 320) can discriminate the smell-prints before and (several time points) after the smoking of 1 cigaretteSecondary Objective(s): Is the effect the same for...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bronchial disorders (excl neoplasms)
Study type	Interventional

Summary

ID

NL-OMON31214

Source
ToetsingOnline

Brief title
VOC in breath: methodological aspects

Condition

- Bronchial disorders (excl neoplasms)

Synonym
airway obstruction, COPD

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Wetenschapsfonds Medisch Centrum Leeuwarden

Intervention

Keyword: COPD, e-nose, methodology, VOC

Outcome measures

Primary outcome

Study 1: the change in smellprint before and after smoking a cigarette.

Study 2: the change in smellprint before, during and after oxygen supply

Study 3: the change in smellprint before and after nebulisation of

salbutamol/ipratropiumbromide

Secondary outcome

not applicable

Study description

Background summary

Asthma and COPD are heterogeneous diseases that are presently diagnosed and monitored by symptoms and physiological measurements. There is recent evidence from clinical follow-up studies that even more detailed (sub)phenotyping of patients can help to optimize therapy and disease outcome. Therefore, the currently required monitoring in asthma and COPD is far from simple, which hampers clinical management.
Diagnostic tests are most often derived from pathophysiological reasoning, and are implemented after determining their test accuracy in diagnostic research. The alternative of pathophysiological reasoning is an empirical approach, in which the diagnostic test is selected based on probabilistic reasoning. The diagnosis of asthma and COPD requires specialized longitudinal lung function measurements and the assessment of responses to inhaled pharmacological agents. There is large room for improvement regarding the accuracy and cost-effectiveness of diagnosing these common lung diseases. The most notable novelty from the past 5-10 years regarding molecular diagnosis in respiratory medicine is the non-invasive analysis of exhaled breath with exhaled nitric oxide (NO) as the best validated exhaled breath marker in lung disease. This was introduced based on pathophysiological reasoning. The current challenge is to combine the simplicity of non-invasive exhaled breath monitoring with the immense potential of unselected, multi-molecule sampling. Such approach might

be labelled as 'breatheomics', and would be based on empirical pattern recognition of molecular markers in exhaled breath. Exhaled breath contains a complex mixture of several hundreds of volatile organic compounds (VOC's). The 'electronic nose' has recently revolutionized the field. These system allows online analysis of VOC's by composite nano-sensor arrays in combination with powerful recognition algorithms. The result of breath sampling by an electric nose is called a *smell-print*. Recently, studies of such an electronic nose have demonstrated promising diagnostic accuracy, both in diagnosing lung cancer and asthma. In order to design good research protocols for the electronic nose in astma and COPD it is important to know if the smell-print is influenced by a couple of very common factors in these diseases (cigarette smoking, oxygen supply and nebulisation with salbutamol/ipratropiumbromide).

Study objective

Study 1.
Primary Objective:
To investigate whether a portable electronic nose system (Cyranose 320) can discriminate the smell-prints before and (several time points) after the smoking of 1 cigarette
Secondary Objective(s):
Is the effect the same for patients with COPD and controls?

Study 2
Primary objective:
To investigate whether a portable electronic nose system (Cyranose 320) can discriminate the smell-prints before, during and (several time points) after 20 min oxygen supply (3L/min)
Secondary Objective(s):
Is the effect the same for patients with COPD and controls?

Study 3
Primary objective:
To investigate whether a portable electronic nose system (Cyranose 320) can discriminate the smell-prints before and (several time points) after nebulisation with salbutamol/ipratropiumbromide
Secondary Objective(s):
Is the effect the same for patients with COPD and asthma?

Study design

open intervention study

Intervention

Study 1 smoking a cigarette

Study 2 intranasal oxygen supply (20 minutes 3 litres/minute)
study 3 nebulisation with salbutamol/ipartropiumbromide (2,5/0,5 microgram)

Study burden and risks

Patients and controls will visit the pulmonary function department one time. They first will complete a questionnaire obtaining information about medical history, smoking history and actual medical condition and then proceed with spirometry. Then exhaled breath collection and after this the intervention will take place (study 1: smoking a cigarette, study 2: intranasal oxygen supply, study 3: nebulisation with salbutamol/ipratropiumbromide). Five more breath samples are taken during the last 90 minutes of the test. Smoking a cigarette is done only in groups that already are smoking more than 10 cigarettes a day. This means the one *test cigarette* will not significantly add any extra harm to the health. Oxygen suppletion will not form a risk for the defined groups and nebulisation of salbutamol/ipratropiumbromide is a well known and usual therapy in patients with asthma and COPD. These groups are chosen to learn about the effects of the interventions on the electronic nose smell-print because we want to design future studies on the value of the electronic nose in COPD and asthma.

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

Study 1;COPD patients:
•Adults between 40-65 years
•Lungfunction: FEV1/VC< 70% and FEV1 30-80%pred. (GOLD II-IV) (21)
•Actual smoker(>10 cigarettes/day, >10 packyears)
Controls:
•Adults between 40-65 years
•Healthy with a negative history on lung diseases or any other illness.
•Prebronchodilator FEV1 > 80% predicted, FEV1/FVC > 0.70 (22)
•Actual smoker(>10 cigarettes/day, > 10 packyears);Study 2;COPD patients:
•Adults between 40-65 years
•Lungfunction: FEV1/VC< 70% and FEV1 30-80%pred (GOLD II-IV) (21)
•Non-smoker(> 1 year, > 10 packyears)
Controls:
•Adults between 40-65 years
•Healthy with a negative history on lung diseases or any other illness.
•Prebronchodilator FEV1 > 80% predicted, FEV1/FVC > 0.70 (22)
•Actual non-smoker(> 1 year);Study 3;COPD patients:
•Adults between 40-65 years
•Lungfunction: FEV1/VC< 70% and FEV1 30-80%pred (GOLD II-IV) (21)
•Non-smoker(>1 year, > 10 packyears)
Asthma patients:
•Adults between 40-65 years
•episodic chest symptoms, documented reversibility in FEV1 by 400 µg inhaled salbutamol > 12 %pred or airway hyperresponsiveness (PC20 methacholine < 8 mg/ml) [15], with or without atopy
•Non-smoker(>1 year,< 10 packyears)

Exclusion criteria

•Other pulmonary diseases
•Pregnancy
•Diabetes mellitus (documented in the past)
•Hypercholesterolaemia (documented in the past)
•Exacerbation < 6 weeks
•Any infection (especially of the airways) in the last 4 weeks

•Inhalation medication < 4 hours
parodontitis

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2007
Enrollment:	150
Type:	Actual

Ethics review

Approved WMO Date:	10-09-2007
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL18497.099.07