Prospective diagnosis of Covid-19 infection using exhaled breath analysis by electronic nose

Published: 16-04-2020
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Objective: The overall aim of this pilot study is to determine the diagnostic accuracy of exhaled breath analysis by eNose for the discrimination between patients and health care workers with and without Covid-19 at point of care.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Observational non invasive

Summary

ID

NL-OMON54883

Source
ToetsingOnline

Brief title
COVINOSE

Condition

- Respiratory tract infections

Synonym
acute respiratory tract infection, flu

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Breathomix,Breathomix betaalt onderzoeksverpleegkundige uurprijs (is het voornemen)

Intervention

Keyword: COVID-19, diagnosis, eNose

Outcome measures

Primary outcome

Main study parameters/endpoints:

Exhaled breath profiles obtained by sampling exhaled air using real time eNose

technology to determine COVID-19 infection

Secondary outcome

To assess the accuracy of exhaled breath analysis by eNose at baseline for

discrimination between individuals with different disease progression (e.g.

mild respiratory symptoms, ICU admission and death).

Study description

Background summary

Rationale:
The World Health Organization (WHO) has recently characterized novel coronavirus (Covid-19) as a pandemic due to its rapid spread and severity. Common clinical symptoms of the disease include fever, cough, shortness of breath. However, in some patients the disease progresses to more severe outcomes as such pneumonia, progressive respiratory failure and even death. Currently, a Reverse Transcription-Polymerase Chain Reaction (rRT-PCR) test is used to detect the virus using e.g. sputum samples. However, results of the test are often available after one to three days. Therefore, there is an urgent need for a diagnostic tool with a rapid turnaround time in processing Covid-19 test results and identify patients with higher risk of fatal outcomes. Exhaled breath analysis using eNose technology linked to a cloud solution may qualify for this.

Study objective

Objective:
The overall aim of this pilot study is to determine the diagnostic accuracy of

exhaled breath analysis by eNose for the discrimination between patients and health care workers with and without Covid-19 at point of care.

Study design

Study design:
Prospective, observational, cross-sectional multi-centre pilot study

Study burden and risks

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
As this concerns observational research using exhaled breath, no direct risk is involved with participation in this study. Participation in this study does not affect the subjects* regular care.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

acute respiratory tract infection, COVID-19 infection

Exclusion criteria

A potential subject who meets any of the following criteria will be excluded from participation in this study:
- Recent (< 12 hours) intake of alcohol
- Unwillingness or inability to comply with the study protocol for any other reason
In order to increase the applicability in clinical practice, there are no further restrictions.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2020
Enrollment:	10300
Type:	Actual

Ethics review

Approved WMO Date:	16-04-2020
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	01-05-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	23-07-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	30-10-2020
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	17-05-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL73555.058.20