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

No registrations found.

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

Summary

ID

NL-OMON25448

Source
Nationaal Trial Register

Brief title
COVINOSE

Health condition

COVID

Sponsors and support

Primary sponsor: LUMC
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

Primary Objectives:
To determine the diagnostic accuracy of exhaled breath analysis by eNose at point of care for discrimination between healthy controls and individuals with respiratory symptoms with

and without a Covid-19 infection.

Secondary outcome

Secondary Objectives:
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 three to four 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.
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 with and without Covid-19 at point of care.
Study design:
Prospective, observational, cross-sectional single-centre pilot study
Study population:
Individuals with a suspected diagnosis of Covid-19 infection.
Main study parameters/endpoints:
Exhaled breath profiles obtained by sampling exhaled air using real time eNose technology.
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.

Study objective

We hypothesize that exhaled breath analysis by eNose is able to discriminate between

patients with and without Covid-19 at point of care.

Study design

day 0 and 30

Intervention

None

Contacts

Public
LUMC
Geert Groeneveld

0715269111
Scientific
LUMC
Geert Groeneveld

0715269111

Eligibility criteria

Inclusion criteria

All newly presented individuals (>18 years of age) and health care personnel with a suspected diagnosis of Covid-19 infection.

Exclusion criteria

- Recent (< 12 hours) intake of alcohol;
- Unwillingness or inability to comply with the study protocol for any other reason.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	17-04-2020
Enrollment:	200
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	10-06-2020
Application type:	First submission

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
NTR-new	NL8694
Other	METC LUMC : P20.033

Study results