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

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We hypothesize that exhaled breath analysis by eNose is able to discriminate between patients with and without Covid-19 at point of care.

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON25448

Bron
Nationaal Trial Register

Verkorte titel
COVINOSE

Aandoening

COVID

Ondersteuning

Primaire sponsor: LUMC
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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.

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

We hypothesize that exhaled breath analysis by eNose is able to discriminate between patients with and without Covid-19 at point of care.

Onderzoeksopzet

day 0 and 30

Onderzoeksproduct en/of interventie

None

Contactpersonen

Publiek

LUMC
Geert Groeneveld

0715269111

Wetenschappelijk

LUMC
Geert Groeneveld

0715269111

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	17-04-2020
Aantal proefpersonen:	200
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Ethische beoordeling

Positief advies

Datum:	10-06-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL8694
Ander register	METC LUMC : P20.033

Resultaten