Remote Early Detection of SARS-CoV-2 infections

Gepubliceerd: 18-02-2021 Laatst bijgewerkt: 18-08-2022

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Ethische beoordeling	Positief advies
Status	Werving gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON23180

Bron
Nationaal Trial Register

Verkorte titel
COVID-RED

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: Universitair Medisch Centrum Utrecht (UMCU), Julius Center
Overige ondersteuning: The COVID-RED project has received funding from the Innovative Medicines Initiative 2 Joint Undertaking under grant agreement No 101005177. This Joint Undertaking receives support from the European Union's Horizon 2020 research and innovation programme and EFPIA.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

SARS-CoV-2 infection (as confirmed through a positive PCR/antigen or serology test)

Toelichting onderzoek

Achtergrond van het onderzoek

It is currently thought that most – but not all – individuals infected with SARS-CoV-2 develop symptoms, but that the infectious period starts on average two days before the first overt symptoms appear. It is estimated that pre- and asymptomatic individuals are responsible for up to half of all transmissions. By detecting infected individuals before they have overt symptoms, the proportion of transmissions by pre-symptomatic individuals could potentially be significantly reduced.
Using laboratory-confirmed SARS-CoV-2 infections (detected via serology tests or SARS-CoV-2 infection tests such as PCR or antigen tests) as the gold standard, we will determine the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for the following two algorithms to detect first time SARS-CoV-2 infection including early or asymptomatic infection:
• the algorithm using Ava bracelet data when coupled with self-reported Daily Symptom Diary data (experimental condition)
• the algorithm using self-reported Daily Symptom Diary data alone (control condition)
In addition, we will determine which of the two algorithms has superior performance characteristics for detecting SARS-CoV-2 infection including early or asymptomatic infection as confirmed by SARS-CoV-2 virus testing.

Doel van het onderzoek

We hypothesize that the algorithm based on the Daily Symptom Diary and bracelet in combination will perform better at detecting SARS-CoV-2 infection in general and, in the case of symptomatic infection, earlier than the algorithm based solely on the Daily Symptom Diary.

Onderzoeksopzet

The primary outcome of the study will be the sensitivity, specificity, positive predictive value and negative predictive value of the developed algorithms (one with the wristband + app and the other just the app) for the detection of new (first time) Covid-19 infection. These outcomes will be measured throughout the study with a final tally calculated at its end.

The secondary outcomes (which I produced by turning the objectives into outcomes) will likewise be monitored throughout the study but a final determination will be made at the end:
· An assessment of the health economic utilization of a wearable device and mobile application
· A measurement of the incidence of SARS-CoV-2 infection during the study

· A list of which features of the Ava bracelet and Daily Symptom Diary are the most predictive
· An assessment of the time from algorithm indication to symptom onset in the subject
· An assessment of the time from algorithm indication to testing of the subject
· A determination of how taking antipyretic medication affects physiological parameters among subjects using the Ava bracelet and Daily Symptom Diary
· A determination of how self-reported vaccinations (other than for COVID-19) cause changes in biophysical parameters from subject's given baseline measurements
· A correlation between the longitudinal symptoms reported by study subjects confirmed to have COVID-19 with changes over time in their physiological data
· A characterisation of longitudinal symptoms and recovery dynamics reported by the study subjects to the presence or absence of lab-confirmed SARS-CoV-2 infection
· An assessment of the adherence to daily symptom diary completion and Ava bracelet wearing and synchronising over time
· An assessment of the impact of the Ava bracelet on adherence to daily symptom diary completion (duration of usage and percentage of days entered)
· A determination of the time necessary to establish baseline physiological parameters per subject in the Learning Phase of the study
· A determination of whether a retrospective identification of the moment of potential SARS-CoV-2 infection is possible for subjects who are seropositive at the end of a period but were negative at baseline and did not receive an alert to get tested during the study
· A determination of how self-reported COVID-19 vaccinations cause changes in biophysical parameters from subject's given baseline measurements
· A determination of the rate of breakthrough and asymptomatic COVID-19 infections among vaccinated individuals
· An assessment of the influence of self-reported COVID-19 vaccinations on compliance to study procedures---

Onderzoeksproduct en/of interventie

Ava COVID-RED app and the Ava bracelet

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Resident of the Netherlands
• At least 18 years old
• Informed consent provided (electronic)
• Willing to adhere to the study procedures described in this protocol
• Must have a smartphone that runs at least Android 8.0 or iOS 13.0 operating systems and is active for the duration of the study (in the case of a change of mobile number, study team should be notified)
• Be able to read, understand and write Dutch

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Previous positive SARS-CoV-2 test result (confirmed either through PCR/antigen or antibody tests) (self-reported)
• Previously received a vaccine developed specifically for COVID-19 or in possession of an appointment for vaccination in the near future
• Current suspected (e.g. waiting for test result) coronavirus infection or symptoms of a coronavirus infection (self-reported)
• Participating in any other COVID-19 clinical drug, vaccine, or medical device trial
• Electronic implanted device (such as a pacemaker)
• Pregnant at time of informed consent (self-reported)
• Suffering from cholinergic urticaria (per the Ava bracelet’s User Manual)
• Staff involved in the management or conduct of this study

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd

Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestopt
(Verwachte) startdatum:	25-02-2021
Aantal proefpersonen:	20000
Type:	Werkelijke startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Ja

Ethische beoordeling

Positief advies

Datum:	18-02-2021
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	NL9320
Ander register	METC UMCU : SL/nb/21/500114

Resultaten