# Remote Early Detection of SARS-CoV-2 infections

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Interventional

## **Summary**

### ID

NL-OMON23180

**Source** Nationaal Trial Register

Brief title COVID-RED

**Health condition** 

COVID-19

## **Sponsors and support**

**Primary sponsor:** Universitair Medisch Centrum Utrecht (UMCU), Julius Center **Source(s) of monetary or material Support:** 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.

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

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

#### Secondary outcome

1. Baseline demographic and risk factors (collected using an online form at subject registration)

2. Epidemiological and infection risk information (collected using bi-weekly online surveys)

3. Self-reported data on time to testing, testing procedures and the results (collected using bi-weekly online surveys)

4. Self-reported data on reception of COVID-19 vaccination (collected using bi-weekly online surveys)

5. Medical event reporting by subjects who have interactions with a general practitioner or a hospital related to SARS-CoV-2 infection, providing healthcare utilization measures during follow-up (collected using bi-weekly online surveys and followed-up by structured phone interviews)

6. Adverse device effects reporting by subjects (collected using bi-weekly online surveys and followed-up by structured phone interviews)

# **Study description**

#### **Background summary**

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.

#### Study objective

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.

#### Study design

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:

 $\cdot$  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

- $\cdot$  An assessment of the time from algorithm indication to symptom onset in the subject
- $\cdot$  An assessment of the time from algorithm indication to testing of the subject

 $\cdot$  A determination of how taking antipyretic medication affects physiological parameters among subjects using the Ava bracelet and Daily Symptom Diary

 $\cdot$  A determination of how self-reported vaccinations (other than for COVID-19) cause changes in biophysical parameters from subject's given baseline measurements

 $\cdot$  A correlation between the longitudinal symptoms reported by study subjects confirmed to have COVID-19 with changes over time in their physiological data

 $\cdot$  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

 $\cdot$  An assessment of the adherence to daily symptom diary completion and Ava bracelet wearing and synchronising over time

 $\cdot$  An assessment of the impact of the Ava bracelet on adherence to daily symptom diary completion (duration of usage and percentage of days entered)

 $\cdot$  A determination of the time necessary to establish baseline physiological parameters per subject in the Learning Phase of the study

 $\cdot$  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

 $\cdot$  A determination of how self-reported COVID-19 vaccinations cause changes in biophysical parameters from subject's given baseline measurements

 $\cdot$  A determination of the rate of breakthrough and asymptomatic COVID-19 infections among vaccinated individuals

 $\cdot$  An assessment of the influence of self-reported COVID-19 vaccinations on compliance to study procedures---

#### Intervention

Ava COVID-RED app and the Ava bracelet

# Contacts

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# **Eligibility criteria**

## **Inclusion criteria**

- 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

## **Exclusion criteria**

• 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

# Study design

## Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	25-02-2021
Enrollment:	20000
Туре:	Actual

### **IPD** sharing statement

#### Plan to share IPD: Yes

# **Ethics review**

Positive opinion	
Date:	
Application type:	

18-02-2021 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	NL9320
Other	METC UMCU : SL/nb/21/500114

# **Study results**