A randomised controlled pilot trial investigating the feasibility of monitoring patients with or at risk for cardiovascular disease who have symptoms suspected of COVID-19 by pulse oximetry at home

Gepubliceerd: 06-10-2020 Laatst bijgewerkt: 18-08-2022

Several weeks of home monitoring of blood oxygen levels of patients with or at risk of cardiovascular disease with moderate to severe symptoms of (presumably) COVID-19 by pulse oximetry might benefit the patient by early detection of hypoxemia, an...

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

Samenvatting

ID

NL-OMON25226

Bron
Nationaal Trial Register

Verkorte titel
CovidSat@Home

Aandoening

Patients presenting to primary care with moderate to severe symptoms of COVID-19 (both SARS-CoV-2 positive and untested patients).

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: De Hartstichting

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Feasibility defined as successful inclusion of 50 participants within 6 months

Toelichting onderzoek

Achtergrond van het onderzoek

Patients with moderate to severe symptoms of (presumably) COVID-19 are monitored at home by their GP using teleconsultation. This leaves the GP with a situation in which he/she has to rely on patients' symptom presentation and subjective assessment of shortness of breath by telephone. It is however known that patients' condition can deteriorate considerably after 7-14 days of symptom onset. Such a deterioratation with corresponding low oxygen saturation levels does often not align with patients' symptoms. In particular patients with overweight, hypertension, diabetes and other cardiovascular risk factors and cardiovascular diseases are at increased risk of a more complicated disease course requiring hospitalisation and sometimes even ICU admission.
Several weeks of home monitoring of blood oxygen levels by pulse oximetry might benefit the patient by early detection of hypoxemia, an important indicator for hospitalisation. In the proposed pilot trial, we perform an early phase evaluation of this new intervention in primary care.

Doel van het onderzoek

Several weeks of home monitoring of blood oxygen levels of patients with or at risk of cardiovascular disease with moderate to severe symptoms of (presumably) COVID-19 by pulse oximetry might benefit the patient by early detection of hypoxemia, an important indicator for hospitalisation. In the proposed pilot trial, we perform an early phase evaluation of this new intervention in primary care.

Onderzoeksopzet

Patients will be followed for 45 days

Onderzoeksproduct en/of interventie

Three times daily (and if needed any additional) measurement of oxygen saturation and pulse rate with a pulse oximeter as added to usual (primary) care versus usual (primary) care.

Contactpersonen

Publiek

Julius Center for Health Sciences and Primary Care, UMC Utrecht
Dorien Zwart

088 75 681 81

Wetenschappelijk

Julius Center for Health Sciences and Primary Care, UMC Utrecht
Dorien Zwart

088 75 681 81

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1) Age ≥40 years
2) Cardiovasculair risk profile or cardiovascular disease (overweight, hypertension, diabetes, smoking, coronary artery disease, previous myocardial infarction, heart failure)
3) Presumably COVID-19 (both SARS-CoV-2 positive and non-COVID-19 confirmed patients)
4) Moderate-severe symptoms
5) Mentally competent

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1) Severe illness requiring hospital admission
2) Patient does not want future hospitalisation
3) Known anemia
4) Inadequate mastery of the Dutch language
5) Not willing to sign informed consent
6) Not willing to adhere to study procedures

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	01-11-2020
Aantal proefpersonen:	50
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:	06-10-2020
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	NL8954
Ander register	METC Utrecht : METC 20-638/D

Resultaten