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

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON25226

Source
Nationaal Trial Register

Brief title
CovidSat@Home

Health condition

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

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: De Hartstichting

Intervention

Outcome measures

Primary outcome

Feasibility defined as successful inclusion of 50 participants within 6 months

Secondary outcome

- the feeling of safety during the first two weeks of illness as reported by the patient
- disability-free survival at 45 days (% change in WHODAS-2 between baseline and day 45)
- number of days alive at home during 45 days after inclusion
- time to discharge from medical follow-up (defined as last contact with healh care professional according to primary care electronic health record data)
- number of primary care contacts during 45 days after inclusion
- number of emergency care department visits during 45 days after inclusion
- proportion of hospitalised patients within 45 days after inclusion
- characteristics of hospital admissions within 45 days after inclusion
o clinical profile at time of hospitalisation (according to the warning signs of Dutch College of General Practitioners)
o length of stay (total and stratified into ward and ICU)
o proportion of patients admitted to ICU
o type of treatments
- 45 day mortality
o overall mortality
o out-of-hospital mortality
o in-hospital mortality

In a parallel process evaluation, we will examine how:
- the intervention has been used in practice in terms of:
(i) Fidelity - whether the intervention was carried out as planned;
(ii) Dose - whether the intervention has been used as long and frequently as planned;
(iii) Adjustments - whether adjustments have been made to the intervention and why;
(iv) Reach - whether the intended audience has been reached and

- the experiences of patients in the intervention group and their informal caregivers in terms of disease perception, fear and use of the intervention
- GPs' experiences with the intervention (usability of pulseoximetry as diagnostic procedure and impact on healthcare utilization)

Study description

Background summary

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.

Study objective

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.

Study design

Patients will be followed for 45 days

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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

Exclusion criteria

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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-11-2020
Enrollment:	50
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Positive opinion

Date:	06-10-2020
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	NL8954
Other	METC Utrecht : METC 20-638/D

Study results