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

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To investigate the feasibility of measuring the oxygen saturation at home by pulse oximetry as added to usual (primary) care in patients with or at risk of cardiovascular risk who have moderate to severe symptoms of (presumably) COVID-19 as compared...

Ethical review	Approved WMO
Status	Completed
Health condition type	Viral infectious disorders
Study type	Interventional

Summary

ID

NL-OMON54917

Source
ToetsingOnline

Brief title
CovidSat@Home

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
COVID-19 and Corona infection

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: de Hartstichting en Stichting Stoffels-Hornstra

Intervention

Keyword: cardiovascular disease, COVID-19, home monitoring, primary care, pulse oximetry

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)

To determine the expression of Neprilysin/CD10 on neutrophil granulocytes in the blood of study participants and to explore its predictive value in terms of

clinical deterioration in COVID-19 patients and whether this expression is

associated with prolonged symptoms in COVID-19 patients.

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. An important process underlying a serious course of COVID-19 is pulmonary edema which may be the result of delayed breakdown of bradykinin. This hypothesis is based on the fact that the virus porte-d'entree is angiotensin-converting enzyme-2 (ACE2) and that this enzyme is down-regulated during virus uptake. Like Neprilysin/CD10 on the neutrophil granulocyte, ACE2 is involved in the regulated degradation of bradykinin. Low expression of Neprilysin/CD10 on neutrophil granulocytes might therefore contribute to increased bradykinin concentration in the lung of COVID-19 patients who also have decreased ACE2 expression.
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

To investigate the feasibility of measuring the oxygen saturation at home by pulse oximetry as added to usual (primary) care in patients with or at risk of cardiovascular risk who have moderate to severe symptoms of (presumably) COVID-19 as compared to usual (primary) care. The aim of the substudy is to determine the Neprilysin/CD10 expression on neutrophil granulocytes in the blood of study participants at baseline and after 3-6 months.

Study design

Individually randomised controlled pilot trial with parallel process evaluation

and two times a venapuncture.

Intervention

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. Comparator: usual (primary) care.

Study burden and risks

The additional risk of using the pulse oxymeter itself and two times a venapuncture are negligible. The pulse oximeter that will be used in this study is validated/approved for medical use and has a CE mark. These will be registered and checked by the MTKF department of the UMC Utrecht for quality assurance purposes. Besides, it is unlikely that measuring oxygen saturation at home together with the (safety) instructions within this study will add any risk for the patient in terms of disease progression and/or mortality. However, this study will be conducted in a vulnerable patient population in which hospital (and ICU) admission and mortality may occur. Therefore, we judged our trial as a negligible risk study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	24-11-2020
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO Date:	06-11-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	16-12-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	12-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	15-07-2021
Application type:	Amendment
Review commission:	METC NedMec

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
CCMO	NL73826.041.20
Other	Trial NL8954

Study results

Date completed: 31-08-2021

Results posted: 28-09-2022

First publication
28-09-2022