CovidTherapy@Home

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory disorders NEC
Study type	Observational non invasive

Summary

ID

NL-OMON22655

Source
Nationaal Trial Register

Brief title
CovidTherapy@Home

Condition

- Respiratory disorders NEC

Health condition

COVID-19; SARS-COV-2 infection

Research involving
Human

Sponsors and support

Primary sponsor: ZilverenKruis
Source(s) of monetary or material Support: ZonMWU
NICUM Huisartsenzorg,
RegiozorgNU,
Huisartsen Utrecht Stad,

Huisartsen Eemland

Intervention

- Other intervention

Explanation

Outcome measures

Primary outcome

Feasibility defined as reaching a stable, regionally supported intervention to monitor and optimally treat patients with COVID-19 (& other RTI) at home with the use of short-cylce evaluation roundes. We will use data of max. 30 patients.

Secondary outcome

We will collect data on patient characteristics, disease course (30 day follow-up, days alive out of hospital) and healthcare use through a combination of inclusion forms, GP medical file extractions, patient monitoring diaries, WHODAS 2.0 patient questionnaires. We will conduct and semi-structured interviews with involved healthcare workers and patients.

Study description

Background summary
The CovidTherapy@Home project focuses on the development and evaluation of a regionally supported, safe, feasible and scalable intervention (both medical and organisational) to optimally treat patients with COVID-19 (or other RTI) and hypoxemia and/or respiratory distress in the home setting. It is desirable to use the available knowledge about the course of the disease in COVID-19 patients to determine whether some of the patients currently admitted to the hospital can be treated safely at home. This prevents the isolation of hospitalisation and relieves hospital care.

Study objective
Action research in which the intervention will be developped trough short-cylce evaluation rounds by the research team together with an expert panel. The initital intervention has been designed based on scientific literature review, practical experience and expert input. This monocenter, observational pilot study concerns the phase of the action research in which we will prospectively collect data from 30 patients in the region to further shape the intervention.

Study design
Monocenter, observational feasibility pilot study

Intervention
Acute home management of respiratory tract infections (COVID-19)

Contacts

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Eligibility criteria

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

Inclusion criteria

Two types of patients can be included.

Type 1:

Patients with RTI/COVID-19 and hypoxemia and/or respiratory distress without signs of clinical instability who normally would be admitted to a hospital ward for supplemental oxygen treatment.

Type 2:

Patients with RTI/COVID-19 and hypoxemia and/or respiratory distress for whom hospitalisation is not considered desirable.

Inclusion criteria:

- Hypoxaemia (SpO2 <94%), and/or respiratory distress (respiratory rate >24/min).

- ≥18 years of age

- Hemodynamically stable

- Support at home: capable family member, or informal caregiver at home

- Able to operate a pulse-oximeter

- Proficient in Dutch (translator is allowed)

Exclusion criteria

Type 1 and 2:

-Dementia or severe psychiatric illness which renders the patient unable to follow study instructions

-Known illness that prevents reliable pulse oximetry, e.g. severe anemia, Raynaud’s disease.

Additional exclusion criteria for type 1

- Clinical condition requires more elaborate care than can be organised at home

- Severe comorbidities or risk factors: COPD GOLD class III or IV; Chronic lung condition

managed by a pulmonologist; insulin-dependent/poorly controlled diabetes; immunocompromised condition; history of deep vein thrombosis or pulmonary embolism; severe heart failure (NYHA III/IV); renal insufficiency (eGFR <30ml/min/1.73 m2); liver failure (Child-Pugh B or C); severe obesity (BMI>35 kg/m2).

Additional exclusion criteria for type 2

- Patient and physician decide -based on shared decision- to withhold specific treatment altogether when considered being in end-stage.

Study design

Design

Study phase:	N/A
Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	03-05-2021
Enrollment:	30
Type:	Actual

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	14-05-2021
Application type:	First submission
Review commission:	METC NedMec

Study registrations

Followed up by the following (possibly more current) registration

ID: 52259
Bron: ToetsingOnline
Titel:

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
NTR-new	NL9459
CCMO	NL77421.041.21
OMON	NL-OMON52259

Study results