COVID-19 Primary care Platform for Early treatment and Recovery (COPPER) Study: an open-label randomized controlled trial

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To evaluate the (cost)effectiveness and safety of early dexamethasone treatment in preventing hospital admission or death and reducing disease severity in patients who are monitored after a GP consultation for deteriorating COVID-19. Because the...

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

Summary

ID

NL-OMON50987

Source
ToetsingOnline

Brief title
COPPER

Condition

- Viral infectious disorders

Synonym
Corona, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: General Practitioners Research Institute
Source(s) of monetary or material Support: Huisartsenzorg Drenthe

Intervention

Keyword: COVID-19, Dexamethasone, Early treatment, Primary care

Outcome measures

Primary outcome

The primary outcome will be time to first hospital admission.

Secondary outcome

Secondary outcomes are time to self-reported recovery, COVID-19 severity and

self-reported disease burden.

Study description

Background summary

The COVID-19 coronavirus has caused a worldwide pandemic of respiratory illness with increased hospital admission and mortality risks. To keep COVID-19 manageable for the healthcare system, early treatment to prevent hospital admission is urgently needed. Dexamethasone as a dampener of an exaggerated cytokine response to COVID-19 is a promising agent to prevent disease worsening, hospital admission, and death. However, evidence about the effectiveness, safety, and cost-effectiveness of dexamethasone treatment in primary care has been inconclusive.

Study objective

To evaluate the (cost)effectiveness and safety of early dexamethasone treatment in preventing hospital admission or death and reducing disease severity in patients who are monitored after a GP consultation for deteriorating COVID-19.

Because the remote monitoring arm is developed for this study, and no information needed for a comprehensive sample size calculation is available, a pilot study will be performed in 50 patients

Study design

The COVID-19 Primary care Platform for Early treatment and Recovery (COPPER) study, is an open-label, adaptive platform, randomised controlled trial. Patients will be randomly assigned (1:1) to the treatment condition

(dexamethasone with safety monitoring of saturation and other signs and symptoms) vs. the control condition (safety monitoring alone) and followed for 28 days intensively, with follow-up questionnaires at 3,6 and 12 months.

Intervention

6 mg dexamethasone prescribed during ten days and as a precaution combined with electronic monitoring of saturation and other signs and symptoms

Study burden and risks

Only capacitated adult patients are deemed eligible. Risk stratification (i.e., selection of patients with moderately severe COVID-19) will prevent overtreatment with dexamethasone of patients who will spontaneously recover and undertreatment of critically ill patients who need to be referred to the hospital. To prevent adverse effects of dexamethasone, co-medication will be prescribed when appropriate according to clinical guidelines. As a safety precaution, worsening of COVID-19 will be tracked by monitoring saturation and other relevant signs and symptoms using a CE certified medical device. SAEs and SUSARS will be carefully assessed. A DSMB will be put in place to ensure a timely discontinuation of the COPPER study if benefits do not outweigh harms.

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

- Age *18 years
- A positive test for SARS-CoV-2
- A GP consultation for deteriorating COVID-19 symptoms
- Exercise-induced desaturation, defined as a drop of *4% in SpO2 and/or to <92% after having performed a 1-minute sit-to-stand test.

Exclusion criteria

- Inability to understand and sign the written consent form
- Inability to perform saturation measurements or sit-to-stand test
- Not willing to be admitted to hospital
- On the discretion of the recruiting clinician if he or she deems a patient not eligible
- Contra-indication for dexamethasone
- History of gastrointestinal bleeding

Study design

Design

Study phase:	4
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):	16-02-2021
Enrollment:	2000
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dexamethasone
Generic name:	Dexamethasone
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	28-01-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	09-02-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

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
EudraCT	EUCTR2021-000235-30-NL
CCMO	NL76634.056.21

Study results

Date completed: 23-04-2021

Results posted: 12-04-2022

Summary results
Trial ended prematurely

First publication
01-01-1900