Physiological effect of the addition of CPAP on top of optimal oxygen supplementation on oxygenation and work of breathing in COVID-19 patients

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The aim is to investigate how effective the addition of several PEEP levels provided by regular CPAP is in patients with COVID-19 with moderate oxygenation problems.

Ethical review	Approved WMO
Status	Will not start
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON49098

Source
ToetsingOnline

Brief title
CPAP in COVID-19

Condition

- Respiratory tract infections

Synonym
Corona virus; SARS-CoV-2

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: COVID-19, CPAP

Outcome measures

Primary outcome

To investigate how effective the addition of several levels of CPAP on top of high oxygen supplementation is on oxygenation, defined peripheral oxygen saturation (SpO2).

Secondary outcome

To investigate how effective the addition of several levels of CPAP on top of high oxygen supplementation is on

- work of breathing, measured with surface EMG and by measuring breathing frequency. EMG mesaurements will be performed with the ExG measurement devoce of ItoM, This device is not CE certified yet, but is extensively tested in healthy persons and has no risks.

- gas exchange: SpO2/FiO2 ratio and transcutaneously measured PtCO2

- Patient dyspnea measured with a Borg scale.

- Patient comfort measured with a Borg scale.

Study description

Background summary

Currently, there are no evidence based pharmacological treatments for COVID-19. Therefore, until now, the most important therapy for COVID-19 is supportive care. The main stain is the provision of high oxygen levels, usually by oxygen masks. Also, high flow oxygen might be beneficial, but viral spread is a problem that is difficult to control with this open system therapy. When patients develop severe lung disease, they are transmitted to the intensive

care unit (ICU) and ventilated invasively via an endotracheal tube with moderate to high PEEP levels, high inspired oxygen fraction (FiO2) and usually low (protective) pressure support levels.
Pathophysiologically, the addition of positive-end-expiratory pressure (PEEP) to high FiO2 might be attractive, also in the phase of moderate to severe hypoxemia at the general ward. This can be delivered with CPAP trough a face mask. CPAP is tried already at large scale in other countries during the COVID-19 epidemic, however without any evidence of its efficacy in this disease.

Study objective

The aim is to investigate how effective the addition of several PEEP levels provided by regular CPAP is in patients with COVID-19 with moderate oxygenation problems.

Study design

The study is an interventional explorative pilot study comparing the effect of 20 minutes of oxygen via a non-rebreathing mask (NRM) with 20 minutes CPAP with 15 L O2/min with different PEEP levels (5, 10 and 15 cm H2O) in random order with 15 minutes interruption periods on the oxygen supplementation on oxygenation and work of breathing.

Intervention

Patients will receive CPAP with high FiO2. With CPAP a continuous airflow is provided through a well-fitting face mask.

Study burden and risks

There is a huge need for non-invasive ventilatory support measures at the general ward during the COVID-19 epidemic, as ICU capacity may become limited and some patients are not being transferred to the ICU because of multiple comorbidities or fragility. By providing an effective additional non-invasive way to support the pulmonary condition of COVID-19 patients we may unload the ICUs and give patients probably a better chance to overcome this disease without ICU admission.
There are no risk known of CPAP. The duration of application is short, so regular side effects with longer-term CPAP use as nasal pressure soars or aerophagia are not expected. Patients may deteriorate with CPAP. However, during the CPAP application one of the investigators will be present all the time and patients can easily be switched to the NRM again. Also, there may be a fear that CPAP may delay ICU admission which may be a disadvantage for the patient. However, application periods are short, patients are very closely monitored and deterioration will be pick-up immediately.

The measurements of oxygenation, transcutaneous PtCO2, heart frequency and respiratory rate and diaphragm muscle activity are all non-invasive and without any risk.

Contacts

Public
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL
Scientific
Universitair Medisch Centrum Groningen

Hanzeplein 1
Groningen 9700RB
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

- > 18 years of age
- proven COVID-19 positive disease
- being admitted to the hospital with oxygenation problems, needing oxygen * 6L/min
- Patients need to be able to read and understand the patient information letter and sign informed consent.

Exclusion criteria

* Patients with severe comorbid pulmonary disease or other diseases leading to hypercapnic respiratory failure
* * Patients in instable condition (hypotensive, cardiac failure/arrhythmia, more than 1 organ failure, upper airway obstruction, very high work of breathing (breathing frequency at rest persistently > 30 breaths/min)
* Unable to fit mask
* Patients who are vomiting
* Agitated, uncooperative patients
* Patients who are unable to protect their airway (for example swallowing impairment)
* Patients with excessive secretions that cannot be managed adequately
* Patients with recent upper airway of upper gastro-intestinal surgery
* Patients with severe skin disease making attachment of the ExG skin electrodes impossible
* Pregnant patients
* Patients not being able to read and understand the patient information letter and sign informed consent.

Study design

Design

Study type:	Interventional
Intervention model:	Other
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	20
Type:	Anticipated

Medical products/devices used

Generic name:	CPAP

Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	13-05-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL73800.042.20
Other	UMCG research register 202000266