Continuous positive airway pressure in severe Covid-19 pneumonia: a feasibility and physiological end-point study

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To evaluate the physiological effects, feasibility, tolerability and safety of CPAP via a face mask in patients with COVID-19 pneumonia requiring high inspired oxygen fractions during spontaneous breathing.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Interventional

Summary

ID

NL-OMON49805

Source
ToetsingOnline

Brief title
CPAP-Covid

Condition

- Respiratory tract infections

Synonym
Corona virus pneumonia, Covid-19

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: NVALT;Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose

Intervention

Keyword: 1. Covid-19, 2. Positive end-expiratory pressure, 3. Noninvasive ventilation, 4. Hypoxaemia

Outcome measures

Primary outcome

The primary endpoint of the study is a change in the combination of oxygen saturation (measured by pulse oximetry, SpO2) and respiratory rate. The use of this combination of variables is substantiated by a recent study showing that the ratio of SpO2 divided by FIO2 (mean inspiratory O2 fraction) and RR are predictors of failure on high flow oxygen therapy. The combination of SpO2 and RR is important as a patient may respond positively through either an improvement of oxygenation (improved ventilation-perfusion matching in the lung or diminished diffusion disorder) or a reduction in respiratory rate.

Secondary outcome

1. Patient satisfaction score and Borg dyspnoea scale

2. System performance: Stability of O2 delivery and CO2 build-up in the mask during the 30-min recording time (measured as the mean inspiratory PO2 and PCO2, respectively).

4. Respiration: minimal negative pressure in the mouth compartment during inspiration (as a measure of inspiratory work of breathing), tidal volume, end-tidal and mixed-expiratory PO2 and PCO2 (as measures of pulmonary gas exchange).

5. Circulation: heart rate, rhythm ECG, continuous finger blood pressure (noninvasive)

6. Neurology: EMV scores

7. Adverse events: painscore, decubitus, CO2 rebreathing, choking, mask

malfunction otherwise

Study description

Background summary

Pneumonia due to SARS-coronavirus 2 (SARS-Cov2, COVID-19) is characterised by bilateral ground-glass opacities comparable with the radiological and clinical characteristics that are often encountered in acute respiratory distress syndrome (ARDS). Patients with COVID-19 pneumonia frequently require high inspiratory oxygen concentrations to avoid hypoxemia. In contrast to ARDS, the compliance of the respiratory system of patients with COVID-19 often remains normal. Therefore, it is postulated that these patients benefit from moderate positive end expiratory pressure (PEEP) to recruit lung tissue and to decrease right-to-left shunt. PEEP can be delivered noninvasively as continuous positive airway pressure (CPAP) via a face mask in conjunction with high inspiratory oxygen fractions.

Study objective

To evaluate the physiological effects, feasibility, tolerability and safety of CPAP via a face mask in patients with COVID-19 pneumonia requiring high inspired oxygen fractions during spontaneous breathing.

Study design

Cross-over phase 1 intervention study. Patients are first monitored during conventional oxygen support via a non-rebreathing mask (standard of care) and are subsequently crossed over to an open-circuit face mask with CPAP 0 cmH2O and the same face mask with CPAP 7.5 cmH2O. Each modality is applied for 30 minutes.

Intervention

Delivery of supplemental oxygen via the face mask with inlet for inspired oxygen delivery and outlet with viral/bacterial filter and a PEEP valve that keeps the system under pressure (7.5 cmH2O).
Three conditions are tested (each lasting 30 min, the *measurement period*):
1. Oxygen delivery via a nonrebreathing mask (current standard of care) with sufficient inflow of O2 (which does not create PEEP).

2. Oxygen delivery via the face mask with zero PEEP in order to test the effect of the mask alone.
3. Oxygen delivery via the face mask with PEEP of 7.5 cmH2O in order to test effect of moderate PEEP.

Study burden and risks

Extent of the burden and risks:
1. Arterial puncture can be painful, in rare cases complications have been described
2. Breathing through a face mask may be uncomfortable. Talking is more difficult and eating and drinking is not possible while wearing the mask.
3. Some people have the tendency to become restless or panic while wearing a mask (a variant of claustrophobia), which may provoke excessive ventilation (hyperventilation).
4. The positive pressure in the mask may also be experienced as uncomfortable
5. Someone who does not breathe easily through the mask may develop hypoventilation, which may aggravate hypoxaemia.

Benefit and group relatedness:
The burden for participation is the exchange of one face mask for another, which might be more or may be less comfortable for the patient. Therefore, the tolerability and safety of the device is also assessed as a secondary outcome of the study. All measurements to obtain the study parameters can be obtained non-invasively and do not impose any discomfort for the patient. The patient can benefit from the treatment by maintaining CPAP therapy when well tolerated, which may result in better oxygenation and less work of breathing. The whole population of hospitalised Covid-19 patients might benefit from this treatment if it is shown to improve oxygenation and respiratory rate as it may prevent the need for intubation and invasive mechanical ventilation. Moreover, as compared to other high flow oxygen devices, it prevents aerosol dispersion into the environment due to the tubing system with an expiratory filter. The setup can be managed relatively easily and can be produced in large quantities.

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
- Positive for Covid-19 (positive nasopharyngeal swab PCR for SARS corona virus 2, with matching abnormalitis on the low-dose CT scan).
- Admitted to Amsterdam UMC, location AMC.
- A transcutaneous O2 saturation (SpO2) of 90% or less at 5 l/min oxygen administration via nasal canula.
- Provide informed consent.

Exclusion criteria

- Hypercapnia (defined as arterial PCO2 > 6.0 kPa or 45 mmHg)
- A history of moderate to severe Chronic Obstructive Pulmonary Disease (COPD, GOLD severity III or IV), restrictive lung disease, or Obesity Hypoventilation Syndrome
- Multi-organ failure
- Need for intubation or admission to the Intensive Care Unit as determined by the responsible physician
- Palliative care
- Reduced consciousness
- Vomiting
- Unability to wear the mask due to anatomical / physical restriction (e.g. facial operations; bearded)

- Unable to provide informed consent.

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-11-2020
Enrollment:	13
Type:	Actual

Medical products/devices used

Generic name:	Continuous positive airway pressure
Registration:	Yes - CE outside intended use

Ethics review

Approved WMO

Date:	20-05-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL73770.018.20
Other	NL8521