Continuous positive airway pressure in severe Covid-19 pneumonia

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28307

Source
NTR

Brief title
CPAP-Covid

Health condition

Corona virus disease 2019 (Covid-19), proven with PCR on nasopharyngeal swab and with matching abnormalities on low-dose CT-scan

Sponsors and support

Primary sponsor: Raad van Bestuur van het AMC (Amsterdam)
Source(s) of monetary or material Support: Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose (NVALT)

Intervention

Outcome measures

Primary outcome

A change in the two-dimensional variable (SpO2, RR), the combination of oxygen saturation and respiratory rate.
SpO2 is measured with a pulse oximeter and RR is derived from the pressure changes in the

mouth compartment of the mask.

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).
3. Respiration: tidal volume, minimal negative pressure in the mouth compartment during inspiration (as a measure of inspiratory work of breathing), end-tidal and mixed-expiratory PO2 and PCO2 (as measures of pulmonary gas exchange).
4. Circulation: heart rate
5. Adverse events: painscore, decubitus, CO2 rebreathing, choking, mask malfunction otherwise

Study description

Background summary

Rationale:
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.
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.
Study population:
Hospitalised COVID-19 patients with a transcutaneous O2 saturation of 90% or less at 5 l/min oxygen administration via nasal canula.
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.
Main study parameters/endpoints:
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.

Study objective

1. The addition of moderate positive end-expiratory pressure (PEEP, 7.5 cmH2O) to high inspiratory fractions of oxygen can either improve oxygenation or reduce respiratory rate, or both, in patients with severe Covid-19 pneumonia
2. The application of moderate positive end-expiratory pressure (7.5 cmH2O) to mentioned patients is feasible with a face mask, reservoir bag and threshold expiration valve.
3. Administration of 100% O2 through a the mentioned face mask (and zero PEEP) improves the oxygenation in patients with severe oxygen-dependent Covid-19 pneumonia as compared with a standard non-rebreathing mask

Study design

After inclusion, there will be a 3 x 30 min measurement episode.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

A subject must meet all of the following criteria:
- age > 18 years
- Positive for Covid-19 (CORADS 5, i.e. highly likely Covid-19 on the low-dose CT scan, or PCR positive nasopharyngeal swab for SARS Coronavirus 2).
- 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
- 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
Intervention model:	Crossover
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	08-05-2020
Enrollment:	13
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Not applicable

Application type:	Not applicable

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
NTR-new	NL8521
Other	METC AMC : METC2020_091#C2020768

Study results