# Continuous positive airway pressure in severe Covid-19 pneumonia

Gepubliceerd: 13-04-2020 Laatst bijgewerkt: 18-08-2022

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...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON28307

**Bron**
NTR

**Verkorte titel**
CPAP-Covid

**Aandoening**

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

### Ondersteuning

**Primaire sponsor:** Raad van Bestuur van het AMC (Amsterdam)
**Overige ondersteuning:** Nederlandse Vereniging van Artsen voor Longziekten en Tuberculose (NVALT)

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

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.

# Toelichting onderzoek

### Achtergrond van het onderzoek

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.

**Doel van het onderzoek**

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

**Onderzoeksopzet**

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

**Onderzoeksproduct en/of interventie**

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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.

# Contactpersonen

## Publiek

Amsterdam UMC, location AMC
Joost van den Aardweg

020-5669111

## Wetenschappelijk

Amsterdam UMC, location AMC

Joost van den Aardweg

020-5669111

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- 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.

# Onderzoeksopzet

## Opzet

Type: Interventie onderzoek

| | |
|---|---|
| Onderzoeksmodel: | Cross-over |
| Toewijzing: | N.v.t. / één studie arm |
| Blindering: | Open / niet geblindeerd |
| Controle: | N.v.t. / onbekend |

### Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 08-05-2020 |
| Aantal proefpersonen: | 13 |
| Type: | Verwachte startdatum |

### Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

**Wordt de data na het onderzoek gedeeld:** Nee

## Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

## Registraties

### Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

### Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

### In overige registers

| Register | ID |
|---|---|
| NTR-new | NL8521 |
| Ander register | METC AMC : METC2020_091#C2020768 |

# Resultaten