Volatile Anaesthetics in COVID-19 – a pilot study

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Using inhaled volatile anaesthetic agents as the primary sedative during mechanically ventilation in patients with COVID-19-associated ARDS improves gas exchange and ventilatory support requirements

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

Samenvatting

ID

NL-OMON27812

Bron
NTR

Verkorte titel
TBA

Aandoening

COVID-19, ARDS

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Internal

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in PaO2/FiO2 (P/F) ratio, oxygenation index, and ventilation parameters

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale:
Recent small studies in ARDS patients indicate that the use of volatile anaesthetic agents can improve oxygenation and decrease levels of a marker of epithelial injury and of some inflammatory markers, when compared with intravenous sedation. We hypothesize that using inhaled volatile anaesthetic agents as the primary sedative during mechanically ventilation in patients with COVID-19-associated ARDS improves gas exchange, ventilatory support requirements, and time to extubation.

Objective:
To investigate the feasibility of inhaled volatile anaesthetic agents in reducing the severity of COVID-19-associated ARDS.

Study design:
Single-centre, pragmatic, open-label, double cross-over randomised controlled pilot trial.

Study population:
Patients with COVID-19 requiring mechanical ventilation.

Intervention:
The administration of inhaled isoflurane for sedation, compared to intravenous sedation. In this pilot study, patients will intermittent receive inhaled or intravenous sedation, according to the randomisation scheme.

Pilot study primary endpoints:
Change in PaO2/FiO2 (P/F) ratio, oxygenation index, and ventilation parameters

Safety endpoints:
Haemodynamic stability, acute liver injury, acute kidney injury

Secondary endpoints:
In-hospital mortality, P/F ratio and oxygenation index at various time points, time to extubation, length of stay in the ICU, length of stay in the hospital, major complications (sepsis, renal failure, MI, stroke, requirement for ECMO, delirium, atrial fibrillation, and myocardial injury).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:
The burden to the patients is minimal: while this intervention is being tested, patients will be already sedated for mechanical ventilation. Furthermore, only routine care data will be used in this pilot study, and there will be no post-discharge follow-up.
Because of its common routine use in clinical anaesthesia, there is extensive experience with the use of isoflurane. The risks of the intervention are considered low and are mainly related the potential side effects of isoflurane, with a lowering effect on blood pressure the most

likely (and very much controllable) side-effect.

Doel van het onderzoek

Using inhaled volatile anaesthetic agents as the primary sedative during mechanically ventilation in patients with COVID-19-associated ARDS improves gas exchange and ventilatory support requirements

Onderzoeksopzet

24, 48, 72 hours, hospital discharge

Onderzoeksproduct en/of interventie

The administration of inhaled isoflurane for sedation, compared to intravenous sedation. In this pilot study, patients will intermittent receive inhaled or intravenous sedation, according to the randomisation scheme.

Contactpersonen

Publiek

UMC Utrecht
Jan Dieleman

+61406982659

Wetenschappelijk

UMC Utrecht
Jan Dieleman

+61406982659

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

• Confirmed or suspected COVID-19

• Respiratory failure requiring mechanical ventilation through an endotracheal tube
• Ventilation using a ventilator that is capable of delivering sevoflurane or isoflurane
• >18 years of age

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

• Suspected or proven intracranial hypertension
• Tidal volume (6 ml/kg predicted body weight [PBW]) less than 250 ml
• Malignant hyperthermia history, or family risk factors
• History of long QT syndrome
• Severe liver failure
• Previous kidney or liver transplantation
• Requirement for extracorporeal mechanical respiratory or circulatory support

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	26-04-2020
Aantal proefpersonen:	20
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	NL8523
Ander register	CCMO : In preparation

Resultaten