Volatile Anaesthetics in COVID-19 – a pilot study

No registrations found.

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

Summary

ID

NL-OMON27812

Source
NTR

Brief title
TBA

Health condition

COVID-19, ARDS

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Internal

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

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).

Study description

Background summary

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.

Study objective

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

Study design

24, 48, 72 hours, hospital discharge

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.

Contacts

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Eligibility criteria

Inclusion criteria

• 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

Exclusion criteria

• 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

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	26-04-2020
Enrollment:	20
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	NL8523
Other	CCMO : In preparation

Study results