

Sleep position related to hospital length of stay in admitted COVID-19 patients

No registrations found.

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

Summary

ID

NL-OMON20126

Source

NTR

Brief title

The PRONE study

Health condition

COVID-19

Sponsors and support

Primary sponsor: None.

Source(s) of monetary or material Support: None.

Intervention

Outcome measures

Primary outcome

Hospital length of stay (days).

Secondary outcome

- In-hospital all-cause mortality

- ICU admission and intubation rate
- ICU admission days
- Oxygen requirement during hospital admission (mean and median FiO₂)
- Percentage of supine sleep time
- Change in oxygen saturation (SpO₂) during supine sleep time

Study description

Background summary

Rationale: Prone positioning improves oxygenation in mechanically ventilated ARDS patients and is currently widely applied in COVID-19 patients in ICUs. Up to 20% of COVID-19 patients on the general ward may require ICU admission for hypoxic respiratory failure and are predominantly admitted during the night. We hypothesize that predominantly sleeping in the non-supine position could improve oxygenation and thereby shorten the disease course.

Objective: To investigate whether non-supine positioning during the night in COVID-19 patients admitted to the hospital ward shortens hospital length of stay.

Study design: Randomized, placebo-controlled single-center study.

Study population: Patients aged ≥ 18 years, admitted to the hospital ward with a proven SARS-CoV-2 infection, suffering from COVID-19.

Intervention (if applicable): Prevent a supine position during sleep by the use of a Sleep Position Trainer, a small wearable device that trains patients to not sleep on their back by using gentle vibrations (1:1 randomization). In both groups sleep position will be continuously registered.

Main study parameters/endpoints: Hospital length of stay (days).

Nature and extent of the burden and risks associated with participation, benefit and group relatedness: Considering the major impact of the COVID-19 pandemic on healthcare systems in the Netherlands but also worldwide, strategies to improve oxygenation and thereby possibly reduce hospital admission days are of major clinical and social importance. Sleep Position Trainers are known to be a safe and patient friendly method of decreasing the proportion of supine sleep time in OSAS patients.

Study objective

Predominantly sleeping in the non-supine position could improve oxygenation and thereby shorten the disease course in admitted COVID-19 patients.

Study design

Admission and hospital discharge.

Intervention

Prevent a supine position during sleep by the use of a Sleep Position Trainer, a small

wearable device that trains patients to not sleep on their back by using gentle vibrations (1:1 randomization). In both groups sleep position will be continuously registered.

Contacts

Public

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Eligibility criteria

Inclusion criteria

- Age \geq 18 years
- Admitted to one of our COVID-19 cohort units
- PCR confirmed COVID-19
- Any form of oxygen therapy (nasal cannula or high-flow nasal oxygen)
- Able to independently change from supine to non-supine position
- Able to read and speak in the Dutch language
- Signed informed-consent
- No current indication for mechanical ventilation

Exclusion criteria

- 'Do not intubate' order

Study design

Design

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

Recruitment

NL	
Recruitment status:	Suspended
Start date (anticipated):	17-04-2020
Enrollment:	342
Type:	Anticipated

IPD sharing statement

Plan to share IPD: Undecided

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	NL8538
Other	METC Franciscus Gasthuis & Vlietland : Not assigned yet.

Study results