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

Gepubliceerd: 17-04-2020 Laatst bijgewerkt: 13-12-2022

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

Ethische beoordeling	Niet van toepassing
Status	Werving tijdelijk gestopt
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20126

Bron
Nationaal Trial Register

Verkorte titel
The PRONE study

Aandoening

COVID-19

Ondersteuning

Primaire sponsor: None.
Overige ondersteuning: None.

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Hospital length of stay (days).

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

Admission and hospital discharge.

Onderzoeksproduct en/of interventie

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.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age ≥ 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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- ‘Do not intubate’ order

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	Placebo

Deelname

Nederland

Status:	Werving tijdelijk gestopt
(Verwachte) startdatum:	17-04-2020
Aantal proefpersonen:	342
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL8538
Ander register	METC Franciscus Gasthuis & Vlietland : Not assigned yet.

Resultaten