PRone positioN in patients with spontanEous ventiLation and acute hypoxemic respIratory FailurE- The PRONELIFE Randomized Controlled Trial

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PRONELIFE is the first randomized controlled trial comparing the prone position with the supine position in patients with acute hypoxemic respiratory failure from any cause that recruits a sufficient number of patients to test the hypothesis that...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON51294

Source
ToetsingOnline

Brief title
ProneLife

Condition

- Other condition
- Thoracic disorders (excl lung and pleura)

Synonym
oxygen, ventilation

Health condition

buikligging ter voorkoming van beademing

Research involving
Human

Sponsors and support

Primary sponsor: OLVG
Source(s) of monetary or material Support: stichting Intensive Care onderzoek OLVG

Intervention

Keyword: intensive care, prone position, spontaneous ventilation

Outcome measures

Primary outcome

The primary endpoint is the number of ventilator-free days at 14 days.

Secondary outcome

Secondary endpoints include the effects of prone position upon oxygenation,

dyspnea, weaning from a respiratory support device, ICU and hospital length of

stay, and mortality at days 28 and 90.

Study description

Background summary

It is uncertain whether the prone position in patients with spontaneous breathing and acute hypoxemic respiratory failure avoids the need for invasive mechanical ventilation. Lung-protective mechanical ventilation with low tidal volumes remains the mainstay management strategy for acute respiratory failure patients and acute respiratory distress syndrome (ARDS). Mechanical ventilation has several detrimental side-effects contributing to morbidity and mortality . Furthermore, tracheal intubation is usually associated with the need for sedation and/or neuromuscular blockade. This precludes mobilization, promotes muscular deconditioning, and potentially contributes to critical illness's long-term cognitive sequelae.

Study objective

PRONELIFE is the first randomized controlled trial comparing the prone position

with the supine position in patients with acute hypoxemic respiratory failure from any cause that recruits a sufficient number of patients to test the hypothesis that the prone position strategy benefits patients with spontaneous breathing and acute respiratory failure concerning a clinically relevant endpoint.

Study design

PRONELIFE is an international multicenter randomized controlled trial in spontaneous breathing patients with acute hypoxemic respiratory failure from any etiology admitted to the ICU. Consecutive patients will be randomly assigned to standard treatment with prone position strategy or standard therapy in the supine position

Intervention

prone position

Study burden and risks

nihil

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 year and older
acute respiratory failure

Exclusion criteria

no informed consent
prone position impossible

Study design

Design

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

Primary purpose: Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2022
Enrollment:	50
Type:	Anticipated

Ethics review

Approved WMO Date:	16-09-2022
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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
ISRCTN	ISRCTN11536318
CCMO	NL79592.100.21