# 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

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## **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

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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**

#### **Public**

**OLVG** 

Oosterpark 9 Amsterdam 1091AC NL **Scientific** 

OLVG

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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