ISRCTN11536318 https://doi.org/10.1186/ISRCTN11536318

A new way to treat patients with respiratory failure: lying on the front while awake

Submission date 15/09/2021	**Recruitment status** Suspended	[X] Prospectively registered [_] Protocol
Registration date 17/09/2021	**Overall study status** Suspended	[_] Statistical analysis plan [_] Results
Last Edited 28/02/2025	**Condition category** Respiratory	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
Intubation is when doctor puts a tube down your throat and into your windpipe to make it easier to get air into and out of your lungs. A machine called a ventilator pumps in air with extra oxygen. Hypoxemic respiratory failure means that you don't have enough oxygen in your blood. It is uncertain whether awake prone positioning (lying on the front) can prevent the need for intubation for invasive ventilation in critically ill patients with acute hypoxemic respiratory failure. Awake prone positioning could benefit these patients for various reasons, including a reduction in direct harm to lung tissue, and prevention of tracheal intubation-related complications.
The aim is to compare standard care with awake prone positioning versus standard care without awake prone positioning in patients with acute hypoxemic respiratory failure.

Who can participate?
Adult patients with acute hypoxemic respiratory failure.

What does the study involve?
Participants will be randomly allocated to be placed into the prone position or to receive treatment as usual. Patients will be followed up for 90 days.

What are the possible benefits and risks of participating?
Expected benefits are patient's symptomatology improvement which can hasten recovery, improve long and short term outcomes, reduce ICU and hospital length of stay.
Possible risk are those associated to the procedure, such as removal of catheter or devices already been in placed, worsening hypoxemia resulting in emergent orotracheal intubation.

Where is the study run from?
Institut d'Investigació i Innovació Parc Taulí (I3PT) (Spain)

When is the study starting and how long is it expected to run for?
September 2019 to January 2025

Who is funding the study?
Institut d'Investigació i Innovació Parc Taulí (I3PT) (Spain)

Who is the main contact?
Dr Luis Morales-Quinteros, luchomq2077@gmail.com

Study website
https://www.esicm.org/endorsed-trials/ongoing-projects-endorsed/#PRONELIFE

Contact information

Type(s)
Scientific

Contact name
Dr Luis Morales-Quinteros

ORCID ID
http://orcid.org/0000-0002-8937-9824

Contact details
Carrer de Sant Quintí, 89
Barcelona
Spain
08041
+34 648493973
luisfernando.morales@vallhebron.cat

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT04142736

Secondary identifying numbers
Nil known

Study information

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

Acronym
PRONELIFE

Study objectives
Awake prone position in patients with acute hypoxemic respiratory failure is associated with a decreased need for intubation

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 08/09/2021, Quiron Salud IRB (CEIm Grupo Hospitalario Quirónsalud-Catalunya. Pedro i Pons, 1 08195 Sant Cugat del Vallès, Barcelona, Spain; +34 93 565 60 00 Ext 5935; ceic.idcsa.cat@idcsalud.es), ref: 2019/68-UCI-HUSC

Study design
International multicenter randomized controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Body position during acute hypoxemic respiratory failure

Interventions
PRONE POSITIONING
The study intervention will last for at least 48 hours and is divided into 4 blocks of 6 hours each: patients will be placed in the prone position for up to 2 hours, which can be prolonged if the patient feels comfortable, but could also be interrupted if a patient meets any of the discontinuation criteria which are any of the following:
developing a contraindication;
worsening of dyspnea (at any time, according to predefined criteria);
a further and sustained drop in SpO2 refractory to an increase in FiO2;
nausea or vomiting; and
increasing hemodynamic instability that is unrelated to sedatives (if given) and cannot be corrected by vasopressor or inotrope infusion

During the change in position, from supine to prone or from prone to supine, FiO2 will be increased by 25% above baseline. Each change in position is guided by two healthcare workers and an attending physician, but more healthcare workers could be needed. While the patient remains in a prone position, skin protection will be used to avoid pressure sores. Also, the

application of cushions will enhance patient tolerance. Arms can be at the side, in a swimmer's position, and can be moved to increase comfort.
Food and comfort breaks are planned while patients are in supine. If the patient is receiving enteral or oral feeding, this is interrupted from 1 hour before prone until a patient is in a supine position.
The best–fitting and most–tolerated oxygen interface will be used in the prone position—this could be different from patient to patient, and different from what is used in the supine position, and could differ between patients but also institutions (i.e., depending on the availability of masks with or without a reservoir bag and with or without the Venturi system, HFNO, CPAP or NIV).

STANDARD OF CARE
In all patients, whether receiving prone positioning or not, the best standard of care is provided, according to the standard care by the local teams.

RANDOMIZATION AND BLINDING
Randomization will be performed using a dedicated password–protected website and will be balanced per center. Central randomization with the use of a permutated–block randomization list (with block sizes of 4 to 8) will be used. Participants will be allocated to the prone positioning or standard care on a 1:1 ratio. By the nature of the intervention it will not be possible to blind clinicians to whether a participant has been randomized to awake prone position or standard care.

Intervention Type
Other

Primary outcome measure
Composite of tracheal intubation and all–cause mortality in the first 14 days after enrolment measured using patient records

Secondary outcome measures
Measured using patient records unless otherwise noted:
1. Mortality at day 14
2. Intubation among survivors at day 24
3. Effects on oxygenation defined by the SpO2 at 4 hours
4. Days under the oxygen support device in 28 days
5. Dyspnea defined according modified Borg dyspnea scale at 4 hours
6. Time to tracheal intubation within 14 days
7. Rate of complications related to prone position at 4 hours:
7.1. Oxygen desaturations (SpO2 <90%)
7.2. Episodes of hemodynamic instability (BPsys < 90mmHg or BPsys drop > 10mmHg if BPsys < 90 before the maneuver)
7.3. Need of orotracheal intubation
7.4. Cardiac arrest
7.5. Displacement of the non-invasive respiratory support device
7.6. Removal of central venous line, if documented
7.7. Displacement of an arterial line, if documented
7.8. Displacement of a urinary catheter, if documented
8. Respiratory rate at 4 hours
9. Duration of invasive mechanical ventilation over 90 days
10. Ventilation-free days (VFD) at 28 days from ICU admission, defined as the number of days

alive and free from IMV during the first 28 days from start of IMV
11. ICU-free days and hospital-free days at day 90
12. Mortality at day 28 and day 90

Overall study start date
04/09/2019

Completion date
01/01/2025

Reason abandoned (if study stopped)
Participant recruitment issue

Eligibility

Key inclusion criteria
1. >18 years
2. Acute respiratory failure from any cause
3. Admitted to a participating ICU
4. Written informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
650

Key exclusion criteria
1. Presence of any contraindication to prone position
2. The patient meets the criteria for intubation
3. Participating in other interventional studies with the same primary outcome
4. Receiving comfort care only
5. Pregnancy

Date of first enrolment
07/02/2022

Date of final enrolment
01/01/2024

Locations

Countries of recruitment
Ecuador

France

Spain

Study participating centre
Hospital de la Santa Creu i Sant Pau.
Carrer de Sant Quintí, 89
Barcelona
Spain
08041

Study participating centre
Hospital Universitari Sagrat Cor.
Carrer de Viladomat, 288
Barcelona
Spain
08029

Study participating centre
Hospital Universitari General de Catalunya.
Carrer Pedro i Pons, 1
Sant Cugat del Vallès
Barcelona
Spain
08195

Study participating centre
Fundació Althaia.
C/ Dr. Joan Soler, 1-3,
Manresa
Barcelona
Spain
08243

Study participating centre
Hospital Vicente Corral Moscoso.
Av. Los Arupos y Av. 12 de Abril
Cuenca

Ecuador
010107

Study participating centre
Centre Hospitalier Universitaire de Lille.
2 Avenue Oscar Lambret
Lille
France
59000

Sponsor information

Organisation
Institute of Research and Innovation Parc Tauli

Sponsor details
Parc del Taulí, 1
Edifici Santa Fe, ala, izquierda, planta 2
Barcelona
Spain
080208
+34 937 23 66 73
lfmoralesq@tauli.cat

Sponsor type
Research organisation

Website
https://www.tauli.cat/es/institut/

ROR
https://ror.org/038c0gc18

Funder(s)

Funder type
Research organisation

Funder Name
Institut d'Investigació i Innovació Parc Taulí (I3PT)

Results and Publications

Publication and dissemination plan
At the appropriate time, and by mutual consent in consultation with the Steering Committee, it is planned that the results of the clinical study will be published in a scientific journal and presented at national and international conferences. Publication of the complete clinical research should generally be the preferred option. The "Uniform requirements for manuscripts submitted to biomedical journals International Committee of Medical Journal Editors" and the Spanish law “Ley Orgánica 3/2018, de 5 de diciembre de Protección de Datos Personales y garantía de los derechos digitales (BOE-A-2018-16673)” will be applied.
All publications will comply with data protection requirements covering patient data and data relating to the participating clinicians. Any publication or presentation of this clinical study results requires prior notification and submission to the Steering Committee for purposes of comment and approval.

Intention to publish date
10/07/2025

Individual participant data (IPD) sharing plan
All data generated or analysed during this study will be included in the subsequent results publication

IPD sharing plan summary
Other