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Prone Positioning and Spontaneous Breathing (PROSE)

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ClinicalTrials.gov Identifier: NCT03768154

Recruitment Status : Not yet recruiting
First Posted : December 7, 2018
Last Update Posted : December 7, 2018

See **Contacts and Locations**

Sponsor:
Osaka University

Collaborator:
Hospital Rebagliati

Information provided by (Responsible Party):
Osaka University

Study Description

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Brief Summary:

Spontaneous breathing during mechanical ventilation has been recommended in patients with ARDS and is currently used. in part because oxygenation is better and there is a lower risk of diaphragm dysfunction due to disuse. The other approach to minimizing lung injury from spontaneous effort is the use of neuromuscular blockade; an early and short term (48 hours) of neuromuscular blockade in patients with severe ARDS has been shown to decrease inflammation and to improve survival. The investigators propose a pilot study to test the feasibility and the physiological effects of allowing spontaneous breathing in the prone position in patients with ARDS.

Condition or disease	Intervention/treatment	Phase
Critical Illness ARDS	Procedure: Supine + spontaneous effort Procedure: Supine + paralysis Procedure: Prone + paralysis Procedure: Prone + spontaneous breathing	Phase 1

Detailed Description:

The multi-center feasibility study will enroll 12 adult ARDS patients from the Intensive Care Units (ICUs) in Japan and Peru. Informed consent will be obtained from the patient or legally authorized substitute decision maker. Moderate-to-severe ARDS patients who are planned to turn to prone positioning, based on the attending physician's decisions will be included. Prior to initiating the protocol, patients will be sedated deeply with sedatives and/or opioids. Ventilator settings, physiological data, esophageal pressure and diaphragm activity will be recorded and physiological measurements will be collected for 5 minutes in supine (Measurement 1: Supine + spontaneous effort) . Patients will be paralyzed with a continuous infusion of rocuronium, and Measurement 2 (Supine + paralysis) will be recorded. The critical care team in the ICU change the position from supine to prone. After waiting for at least 1 hour in prone positioning, Measurement 3 (Prone + paralysis) will be recorded. Continuous infusion of rocuronium will be gradually decreased (and can be terminated) until spontaneous breathing will be observed without reaching an excessive level. The presence of spontaneous breathing will be evaluated by the negative swing of esophageal pressure, and Measurement 5 (Prone + spontaneous breathing) will be recorded.

Study Design

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Study Type :	Interventional (Clinical Trial)
Estimated Enrollment :	12 participants
Intervention Model:	Sequential Assignment
Intervention Model Description:	Measurement 1 (Supine + spontaneous effort) , Measurement 2 (Supine + paralysis) , Measurement 3 (Prone + paralysis) , Measurement 4 (Prone + spontaneous breathing)
Masking:	None (Open Label)
Primary Purpose:	Treatment
Official Title:	Prone Positioning and Spontaneous Breathing: a Feasibility Study
Estimated Study Start Date :	December 1, 2018
Estimated Primary Completion Date :	March 31, 2021
Estimated Study Completion Date :	March 31, 2021

Arms and Interventions

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Arm	Intervention/treatment
Experimental: study arm all patients will receive all four intervention in the same sequential method	Procedure: Supine + spontaneous effort without muscle paralysis in supine position

	Procedure: Supine + paralysis administer muscle paralysis in supine position Procedure: Prone + paralysis change the patient position from supine to prone with muscle paralysis Procedure: Prone + spontaneous breathing cease the paralysis in supine position

Outcome Measures

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Primary Outcome Measures :

1. spontaneous breathing [Time Frame: Through study completion (up to 24 hours)]

   Presence of spontaneous breathing while patients are under prone positioning.

Secondary Outcome Measures :

1. inflammatory cytokines [Time Frame: Through study completion (up to 24 hours)]

   IL-6, IL-8 levels

2. Trans-pulmonary pressure [Time Frame: Through study completion (up to 24 hours)]

   Trans-pulmonary pressure

3. electrical activity of diaphragm [Time Frame: Through study completion (up to 24 hours)]

   electrical activity of diaphragm

4. lung recruitment volume [Time Frame: Through study completion (up to 24 hours)]

   lung recruitment volume

Eligibility Criteria

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Information from the National Library of Medicine NIH NLM

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the contacts provided below. For general information, Learn About Clinical Studies.

Ages Eligible for Study:	18 Years and older (Adult, Older Adult)
Sexes Eligible for Study:	All
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Patients ≧ 18 years old
- Patients with moderate-to-severe ARDS as per the Berlin definition
- Patients with esophageal balloon manometry
- Patients planned to turn to prone positioning, based on the attending physician's decisions

Exclusion Criteria:

- Contraindication for prone positioning, referring to a previous randomized clinical trial
    1. Intracranial pressure >30 mm Hg or cerebral perfusion pressure <60 mmHg
    2. Massive hemoptysis requiring an immediate surgical or interventional radiology procedure
    3. Tracheal surgery or sternotomy during the previous 15 days
    4. Serious facial trauma or facial surgery during the previous 15 days
    5. Cardiac pacemaker inserted in the last 2 days
    6. Unstable spine, femur, or pelvic fractures
- Major hemodynamic instability:

Mean arterial pressure lower than 60 mm Hg despite adequate fluid resuscitation and two vasopressors or increase of vasopressor dose by 30% in the previous 6 hours.

- Contraindication to EIT electrode placement Burns, chest wall bandaging limiting electrode placement, pacemaker
- Clinical judgement of the attending physician against proning and/or spontaneous breathing

Contacts and Locations

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Information from the National Library of Medicine NIH NLM

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Please refer to this study by its ClinicalTrials.gov identifier (NCT number): ***NCT03768154***

Contacts

Contact: Takeshi Yoshida, PhD +81668795820 takeshiyoshida@hp-icu.med.osaka-u.ac.jp

Sponsors and Collaborators

Osaka University

Hospital Rebagliati

Investigators

Principal Investigator: Takeshi Yoshida, PhD Osaka University

More Information

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Responsible Party:	Osaka University
ClinicalTrials.gov Identifier:	NCT03768154 History of Changes
Other Study ID Numbers:	PROSE2018
First Posted:	December 7, 2018 Key Record Dates
Last Update Posted:	December 7, 2018
Last Verified:	December 2018

Individual Participant Data (IPD) Sharing Statement:

Plan to Share IPD: No

Studies a U.S. FDA-regulated Drug Product:	No
Studies a U.S. FDA-regulated Device Product:	No

Keywords provided by Osaka University:

spontaneous breathing

prone position

muscle paralysis

Additional relevant MeSH terms:

Respiratory Aspiration	Respiratory Tract Diseases
Critical Illness	Pathologic Processes
Respiration Disorders	Disease Attributes