

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Aug 2026

Evaluation of Ultrasonographic lung Recruitibility with Two Types of Positive End Expiratory Pressure Selection in Moderate to Severe Acute Respiratory Distress Syndrome

Protocol summary

Study aim

Determination of ultrasonographic lung recruitibility with two type of positive end expiratory pressure (PEEP) titration in Acute respiratory distress syndrome (ARDS)

Design

A quasi-experimental study with "before and after" design with a sample size of 15 patients and without randomization

Settings and conduct

This study will be done in Mashhad University of medical sciences, Emam Reza hospital and in intensive care unit. Diagnosis and selection of patients with acute respiratory distress syndrome and also other stages of the study including lung ultrasonography will be done by the fellowship of critical care medicine.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Moderate to severe ARDS patients (based on Berlin criteria), older than 18 and under invasive mechanical ventilation
Exclusion criteria: Known heart failure or acute ischemic heart disease, chronic respiratory disease, increased intracranial pressure, morbid obesity

Intervention groups

In this study, 15 patients with moderate to severe ARDS who need invasive mechanical ventilation will be selected. Initially, patients will be ventilated according to ARDS net protocol and positive end expiratory pressure (PEEP) selection will be based on the lowest recommended level in the "low PEEP table", then lung aeration will be assessed by ultrasonography. After 30 minutes, PEEP level will be adjusted according to EXPRESS trial and assessment of lung aeration by ultrasonography will be repeated. Both types of PEEP selection will be applied to each patient and in fact, control and intervention group are the same.

Main outcome variables

lung recruitment (Reaeration) according to sonographic

criteria

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150427021981N1**

Registration date: **2018-04-04, 1397/01/15**

Registration timing: **registered_while_recruiting**

Last update: **2018-04-04, 1397/01/15**

Update count: **0**

Registration date

2018-04-04, 1397/01/15

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 38023763

Email address

bagheria@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2018-04-21, 1397/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of Ultrasonographic lung Recruitibility with Two Types of Positive End Expiratory Pressure Selection in Moderate to Severe Acute Respiratory Distress Syndrome

Public title

Ultrasonographic Evaluation of lung Recruitibility in Acute Respiratory Distress Syndrome

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with Moderate to Severe Acute Respiratory Distress Syndrome and under invasive mechanical ventilation

Exclusion criteria:

Younger than 18 year Less than 24 h or more than 96 h after the onset of the disease. Unstable hemodynamic Contraindication for using of high PEEP Known heart failure Acute ischemic heart disease or uncontrolled arrhythmia Chronic lung disease BMI>40

Age

From 18 years old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: 15

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

This study is quasi-experimental with "before-after" design.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of mashhad university of medical sciences

Street address

ghoreishi building,daneshgah street,Mashhad

City

Mashhad

Province

Razavi Khorasan

Postal code

91375-345

Approval date

2017-07-09, 1396/04/18

Ethics committee reference number

IR.MUMS.fm.REC.1396.488

Health conditions studied

1

Description of health condition studied

Acute Respiratory Distress Syndrome

ICD-10 code

J80

ICD-10 code description

Acute respiratory distress syndrome

Primary outcomes

1

Description

lung recruitibility (Reaeration) with two type of positive end expiratory pressure selection

Timepoint

Initial measurement of lung recruitment (Reaeration) with a low level of positive end expiratory pressure (low PEEP table) and after 30 minutes with a high positive end expiratory pressure level (Express trial)

Method of measurement

By lung ultrasonography with 2.5 to 5 megahertz curve probe

Secondary outcomes

1

Description

Oxygenation state

Timepoint

Five minutes after positive end expiratory pressure (PEEP) change

Method of measurement

Dividing the arterial oxygen pressure to the fraction of inspired oxygen (Po2/Fio2 ratio)

Intervention groups

1

Description

Intervention and control group: Use of positive end expiratory pressure according to "low PEEP table" in ARDS net protocol during mechanical ventilation (control group) and then (after 30 minutes), Use of positive end expiratory pressure according to recommended level in

"Express trial" in the same patient (intervention group)
Category
Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Emam reza hospital, Intensive care unit
Full name of responsible person
Ahmad bagheri moghaddam
Street address
Emam reza hospital, Emam reza square, Mashhad
City
Mashhad
Province
Razavi Khorasan
Postal code
9137913316
Phone
+98 51 3854 3031
Email
bagheriA@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen tafaghodi
Street address
Daneshgah Ave
City
Mashhad
Province
Razavi Khorasan
Postal code
91375-345
Phone
+98 51 3841 1538
Email
vcresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ahmad bagheri moghaddam
Position
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Critical care
Street address
No.187, yasaman 6 Ave, sajjad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
9186684736
Phone
+98 51 3760 6328
Email
bagheriA@mums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Ahmad bagheri moghaddam
Position
Assitant professor
Latest degree
Subspecialist
Other areas of specialty/work
critical care
Street address
No.187, Yasaman 6 Ave, Sajjad Blvd
City
Mashhad
Province
Razavi Khorasan
Postal code
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Phone
+98 51 3760 6328
Email
bagheriA@mums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person

Ahmad bagheri moghaddam

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Assistant professor

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available