Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of atelectasis and PaO_2 / FiO_2 ratio in lung contusion patients treated with reservoir bag mask and non-invasive ventilation mask: A Randomized Control Trial.

Protocol summary

Study aim

1. Comparison of atelectasis rate and PaO_2 / FiO_2 ratio (P/F ratio) in patients with lung contusion treated with reservoir bag and Non-invasive ventilation (NIV) mask.

Design

A prospective randomized clinical trial study to compare 2 treatment methods. With a control group with parallel groups, single-blind, phase I on 128 patients.

Settings and conduct

The aim of this study is to compare the effectiveness of two non-invasive oxygen therapy methods, including a reservoir bag mask and non-invasive ventilation (NIV), on the severity of lung atelectasis and the PaO_2/FiO ratio (P/F ratio) in patients with lung contusion due to blunt chest trauma. Study location and time: This study will be conducted at Madani Hospital between 2014 and 2015. The study population includes all adult patients (18 years and older) who refer to Madani Hospital for blunt chest trauma and are diagnosed with lung contusion based on clinical findings and CT scan imaging. The study sample includes eligible hospitalized patients who, after obtaining informed consent, are randomly assigned to one of the two reservoir bag mask or non-invasive ventilation (NIV) groups.

Participants/Inclusion and exclusion criteria

The study population consists of all adult patients (18 years and older) who refer to Madani Hospital for blunt chest trauma during the years 2014 to 2015 and are diagnosed with lung contusion based on clinical examinations and imaging (CT Scan).

Intervention groups

1: Reservoir Bag mask group 2:Non-invasive ventilation group (NIV)

Main outcome variables

Severity of lung atelectasis based on chest CT scan and standard scoring system (Atelectasis Severity Score) - PaO_2/FiO_2 ratio - Need for endotracheal intubation - Length of hospital stay - Adverse clinical outcomes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260214068848N1**
Registration date: **2026-04-20, 1405/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2026-04-20, 1405/01/31**
Update count: **0**

Registration date

2026-04-20, 1405/01/31

Registrant information

Name

Ali Mohammadi Arani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 26 3419 7000

Email address

alimohamadi371@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2026-03-21, 1405/01/01

Expected recruitment end date

2026-08-23, 1405/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Evaluation of atelectasis and PaO_2 / FiO_2 ratio in lung contusion patients treated with reservoir bag mask and non-invasive ventilation mask: A Randomized Control Trial.

Public title
Evaluation of atelectasis in lung contusion patients treated with reservoir bag mask and NIV mask.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of lung contaminant on chest CT scan PaO_2/FiO ratio less than 300 mmHg Hemodynamic stability (no or low dose vasopressor requirement) Adequate level of consciousness (GCS = 15) No immediate need for endotracheal intubation Ability to tolerate NIV mask

Exclusion criteria:
Severe hemodynamic instability Decreased level of consciousness Fractures of more than 3 ribs Presence of concurrent hemothorax or pneumothorax Severe skull or facial fracture that prevents the use of an NIV mask Active upper airway bleeding Having underlying lung conditions (such as COPD or asthma) Presence of significant underlying heart disease, pregnancy, need for abdominal surgery Intolerance to non-invasive ventilation or failure of non-invasive therapy Request by patient or legal guardian to withdraw from the study

Age
From **18 years** old

Gender
Both

Phase
1

Groups that have been masked
No information

Sample size
Target sample size: **128**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization was performed using a table of random numbers. After confirming eligibility, each patient was assigned a number from the random number table and allocated to either the Reservoir Bag Mask group or the NIV Mask group according to a predetermined sequence. This method was used to minimize selection bias and ensure an unbiased distribution of participants between the two groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Alborz University of Medical Sciences

Street address
Taleghani

City
Karaj

Province
Alborz

Postal code
3147734568

Approval date
2026-01-31, 1404/11/11

Ethics committee reference number
IR.ABZUMS.REC.1404.345

Health conditions studied

1

Description of health condition studied
Lung contusion

ICD-10 code
S27.32

ICD-10 code description
Contusion of lung

Primary outcomes

1

Description
P/F ratio

Timepoint
5th and 10th day

Method of measurement
ABG

2

Description
Atelectasis severity

Timepoint
24 hours- 5th day- 10th day

Method of measurement
CT-scan

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Non-invasive ventilation
Category
Treatment - Other

2

Description
Control group: Reservoir bag mask
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Madani Hospital
Full name of responsible person
Ali Mohammadi Arani
Street address
Taleghani
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3147734568
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Karaj University of Medical Sciences
Full name of responsible person
Mojtaba Ahmadinejad
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3147734568
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abzums@domain.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Karaj 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
Karaj University of Medical Sciences
Full name of responsible person
Ali Mohammadi Arani
Position
Resident
Latest degree
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General Surgery
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Person responsible for updating data

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
Article
When the data will become available and for how long
from 2026
To whom data/document is available
Researchers
Under which criteria data/document could be used
Permission of corresponding author
From where data/document is obtainable
Ali Mohammadi Arani
What processes are involved for a request to access data/document
email
Comments