

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Aug 2026

The comparison of the incidence of atelectasis, pleural effusion and pneumonia in patients without ALI-ARDS with two methods of ventilation, normal ventilation and ventilation with open lung concept

Protocol summary

Summary

The aim of study was to compare two methods of ventilation, normal ventilation and ventilation with open lung concept, among patients without ALI-ARDS regarding the incidence of atelectasis, pleural effusion and pneumonia. Forty two intubated patients in Sina hospital ICU ward, who were considered to have mechanically ventilation for at least one week, were allocated into 2 groups. Control group were ventilated with the below setting: PS:5-10, FIO2:50%, PEEP=5cmH2O, TV=6cc/kg, mode: SIMV. Intervention group were ventilated with below setting: PS: 5-10, FIO2:50%, PEEP=8cmH2O, TV=6cc/kg, mode: SIMV. In addition, intervention group were ventilated with APRV mode 10 minutes every 4 hours at pressure of 40 cmH2o during the study. CBC, SOFA, compliance and airway resistance were monitored daily in all patients. CRP was evaluated 3 times and cardiac monitoring 2 times during the study. Pulmonary CT scan were done at the start and the end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012122211840N1**

Registration date: **2013-02-08, 1391/11/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2013-02-08, 1391/11/20

Registrant information

Name

Fatemeh Heidari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 6649 5936

Email address

heydari_f@razi.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran university of medical sciences

Expected recruitment start date

2013-01-01, 1391/10/12

Expected recruitment end date

2013-04-04, 1392/01/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the incidence of atelectasis, pleural effusion and pneumonia in patients without ALI-ARDS with two methods of ventilation, normal ventilation and ventilation with open lung concept

Public title

The comparison of the incidence of atelectasis, pleural effusion and pneumonia in patients without ALI-ARDS with two methods of ventilation, normal ventilation and ventilation with open lung concept

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: 1) Pao2/FIO2>350; 2) age 20-65 yrs.

Exclusion criteria: 1) pneumonia; 2) Heart failure; 3) History of lung disease (asthma, COPD, Bronchiectasia); 4) ALI; 5) ARDS; 6) patient or families refusal.

Age

From **20 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **42**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

School of Medicine, north side of Tehran University,
Poursina Street

City

Tehran

Postal code

1417613151

Approval date

2012-11-26, 1391/09/06

Ethics committee reference number

17969/210/91/3

Health conditions studied

1

Description of health condition studied

Atelectasis

ICD-10 code

J98

ICD-10 code description

Other respiratory disorders

Primary outcomes

1

Description

Pneumonia

Timepoint

at the beginning and 7 days later

Method of measurement

Symptoms of pulmonary critical-CT Scan - leukocytosis -
culture of respiratory secretions

Secondary outcomes

1

Description

Hemodynamics

Timepoint

Every 4 hours for 7 days

Method of measurement

Heart Monitor, Blood Pressure Meter, Thermometer,
Pulse oximetry

Intervention groups

1

Description

Control group were ventilated with the below setting:
PS:5-10, FIO2:50%, PEEP=5cmH2O, TV=6cc/kg, mode:
SIMV

Category

Prevention

2

Description

Intervention group were ventilated with below setting:
PS: 5-10, FIO2:50%, PEEP=8cmH2O, TV=6cc/kg, mode:
SIMV.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital ICU

Full name of responsible person

Dr Fatemeh Heidari, Assistant Anesthesiology and
Intensive Care

Street address

Sina hospital, Imam Khomeini St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Akbar Fotouhi

Street address

Poursina Street - north side of Tehran University -
School of Medicine

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Arezo Ahmadi

Position

Assistant Professor of Anesthesia and Intensive Care

Other areas of specialty/work

Street address

Sin Hospital, Imam Khomeini Avenue

City

Tehran

Postal code

4691111367

Phone

+98 21 2290 1137

Fax

Email

areezo24@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Atabak Najafi

Position

Associate Professor of Anesthesia and Intensive Care

Other areas of specialty/work

Street address

Imam Khomeini

City

Tehran

Postal code

Phone

+98 21 6312 0000

Fax

Email

nadjafiha@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr Fatemeh Heidari

Position

Assistant Anesthesiology and Intensive Care

Other areas of specialty/work

Street address

Sina hospital, Imam Khomeini St

City

Tehran

Postal code

4691111367

Phone

+98 21 6646 4924

Fax

Email

heydari_f@razi.tums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty