

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

The effect of manual lung hyperinflation on pulmonary function and incidence of atelectasis in patients undergoing abdominal surgery and T-tube support

Protocol summary

Summary

This study is conducted for evaluating the effect of manual lung hyperinflation on pulmonary function and incidence of atelectasis in patients who supported by t-tube after abdominal surgery in training centers, research and treatment of Imam Reza and Ghaem hospitals in Mashhad. In this study 40 patients who had undergone abdominal surgery randomly allocated to groups of experimental and control. Patients who were allocated in experimented group were be received pulmonary hyperinflation by using Mapleson C for two hours. Patients who were allocated in control group were be received the hospital routine treatment. For comparing the outcomes of two groups, we assessed the results of atrial blood gases, partial pressure arterial oxygen and fraction of inspired oxygen, rapid shallow breathing index (RSBI), and chest x-ray in two groups with each other.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015103024790N1**
Registration date: **2016-06-01, 1395/03/12**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-01, 1395/03/12

Registrant information

Name

Mahboube Yazdani

Name of organization / entity

Nursing and Midwifery Mashhad University

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2015-09-23, 1394/07/01

Expected recruitment end date

2016-03-19, 1394/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of manual lung hyperinflation on pulmonary function and incidence of atelectasis in patients undergoing abdominal surgery and T-tube support

Public title

Manual Lung Hyperinflation and its effect on pulmonary function and lung atelectasis

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Patients are older than 18; Lack of pulmonary disorders such as Acute respiratory distress syndrome, pneumothorax, acute pulmonary edema and hemoptysis; Absence of acute infection; No history of acute Cardiovascular disorders; Patients underwent

abdominal surgery; Patients should be supported by t-tube after weaning mechanical ventilation at least 2 hours; No emergency surgery or Cardiopulmonary resuscitation(CPR) before intervention; Having the ratio of partial pressure arterial oxygen and fraction of inspired oxygen more than 200; Absence of electrolyte disorders. Exclusion Criteria: Need to get Cardiopulmonary resuscitation (CPR); Need to support by mechanical ventilation; Rise in Intracranial Pressure (ICP); Severe hemodynamic impairment; Lack of patients cooperation such as agitation; Patients who Need to reoperation or extubation

Age

From **18 years** old to **85 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Using a random number table for randomization

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah Street, Qureshi Building

City

Mashhad

Postal code

Approval date

2015-06-07, 1394/03/17

Ethics committee reference number

IR.MUMS.REC.1394.247

Health conditions studied

1

Description of health condition studied

Respiratory complications after abdominal surgery

ICD-10 code

J95.2

ICD-10 code description

Acute pulmonary insufficiency following nonthoracic surgery

Primary outcomes

1

Description

Partial pressure of Oxygen (PaO2)

Timepoint

Before, 5 and 20 minutes after intervention

Method of measurement

Arterial blood gas samples

2

Description

PaCO2

Timepoint

Before, 5 and 20 minutes after intervention

Method of measurement

Arterial blood gas samples

3

Description

Estimate of arterial oxygen saturation(SaO2)

Timepoint

Before, 5 and 20 minutes after intervention

Method of measurement

Pulse oxymetry

4

Description

Scoring atelectasis

Timepoint

Before and after intervention

Method of measurement

Chest X ray

5

Description

ratio of partial pressure arterial oxygen and fraction of inspired oxygen(PaO2/FiO2)

Timepoint

Before, 5 and 20 minutes after intervention

Method of measurement

Putting data in the formula

6

Description

Ratio of respiratory frequency to tidal volume(RSBI)

Timepoint

Before, 5 and 20 minutes after intervention

Method of measurement

Putting data in the formula

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After suctioning and doing arterial blood gases and chest X-ray, for two hours, hyperinflation were done. At the end of two hours, all parameters were at the beginning of intervention were recorded

Category

Other

2

Description

Control group: All actions in the intervention group without executing the manual lung hyperinflation were done.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Street address

Ahmad Abad Street

City

Mashhad

2

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Street address

West Ebn-e-Sina Street

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaqodi

Street address

Qureshi Building, Before Golestan Intersection, Daneshgah Street

City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Mashhad University of Medical Sciences and Health Services

Full name of responsible person

Javad Malekzadeh

Position

Bachelor' degree of nursing education, faculty

Other areas of specialty/work

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Mashhad University of Medical Sciences and Health Services

Full name of responsible person

Mahboube Yazdani

Position

Student

Other areas of specialty/work**Street 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