Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

A clinical trial to compare the effectiveness of administration of the one third of intraoperative fluid with standard amount of fluid on pulmonary complications after lobectomy of left lung

Protocol summary

Study aim

To compare the effectiveness of administration of the one third of intraoperative fluid with standard amount of fluid on pulmonary complications after lobectomy of left lung

Design

This randomized and double-blind clinical trial with parallel and control groups will be conducted on 140 patients who will be randomly selected using the random number table.

Settings and conduct

Patients candidate for lobectomy of left lung referring to Ghaem Hospital, Mashhad, Iran are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the one third of intraoperative fluid and control will receive standard amount of fluids. The participants and responsible for data collection are blind to group allocation and the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with ASA I, II or III, who are candidate for lobectomy of left lung; not having cardiovascular disease; not having kidney failure; not having systemic disease such as diabetes, hypertension and thyroid disease. Exclusion criteria: Receiving high intraoperative blood transfusion volume greater than 50 percent of the total blood volume of patient during three hours; receiving diuretics and osmotic substances before surgery; patient cardiopulmonary arrest.

Intervention groups

The intervention group will receive midazolam, fentanyl and propofol to induce anesthesia, then will receive one third of fluid maintenance during surgery. The control group will receive midazolam, fentanyl and propofol to induce anesthesia, then will receive standard rate of fluid maintenance during surgery.

Main outcome variables

Evaluation the total fluid rate injection during intraoperative, duration of anesthesia, duration of hospitalization, pulmonary complications and mortality rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220627055294N1**
Registration date: **2022-06-30, 1401/04/09**
Registration timing: **prospective**

Last update: **2022-06-30, 1401/04/09**
Update count: **0**

Registration date

2022-06-30, 1401/04/09

Registrant information

Name
Mandana Jahanian
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2023-08-23, 1402/06/01

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A clinical trial to compare the effectiveness of administration of the one third of intraoperative fluid with standard amount of fluid on pulmonary complications after lobectomy of left lung

Public title
The effectiveness of the amount of intraoperative fluid administration on pulmonary complications after lobectomy of left lung
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with ASA I, II or III, who are candidate for lobectomy of left lung Not having cardiovascular disease Not having kidney failure Not having systemic disease such as diabetes, hypertension and thyroid disease
Exclusion criteria:
Receiving high intraoperative blood transfusion volume greater than 50 percent of the total blood volume of patient during three hours Receiving diuretics and osmotic substances before surgery Patient cardiopulmonary arrest
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **140**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, simple randomization will be used by random number table based on SAS (statistical analysis system), software. A list of sequentially number 1 to 10 will be created. This list will assign numbers randomly by computer. Patients are randomly assigned according to the numbers of this list. To conceal, we use allocation concealment, using non-transparent envelopes sealed with random sequences (Sequentially numbered, sealed, opaque envelopes). They are placed in order. In order to maintain the random sequence, numbering is done on the outer surface of the envelopes in the same way. Finally, the lids of the envelopes are glued and placed inside a box, respectively. At the beginning of the registration of participants, based on the order of entry of eligible participants in the study, one of the envelopes will be opened in order and the assigned group of the participant will be revealed.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients candidate for lobectomy of left lung referring to Ghaem Hospital, Mashhad, Iran are chosen as the participants of the study. In this double-blind study, sealed opaque envelopes will be used to conceal the sequencing. Intervention group will receive the one third of intraoperative fluid and control will receive standard amount of fluids. The participants and responsible for data collection are blind to group allocation and the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences
Street address
Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
9195965919
Approval date
2022-05-31, 1401/03/10
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.176

Health conditions studied

1

Description of health condition studied
Pulmonary complications after lobectomy
ICD-10 code
J95.3
ICD-10 code description
Chronic pulmonary insufficiency following surgery

Primary outcomes

1

Description

The total fluid rate injection during intraoperative

Timepoint

During surgery

Method of measurement

Total volume of injected fluids in cc per kg

2

Description

Duration of anesthesia

Timepoint

After intervention

Method of measurement

The number of hours of postoperative anesthesia

3

Description

The duration of hospitalization

Timepoint

Two weeks after intervention

Method of measurement

The number days of hospitalization

4

Description

Pulmonary complications (acute respiratory distress syndrome, intubation, atelectasis, pneumonia, persistent air leaks)

Timepoint

48 hours after intervention

Method of measurement

Based on clinical examinations

5

Description

Mortality rate

Timepoint

48 hours after intervention

Method of measurement

Calculating a mortality rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The intervention group will receive midazolam, fentanyl and propofol to induce anesthesia, then will receive one third of fluid maintenance during surgery.

Category

Prevention

2

Description

Control group: The control group will receive midazolam, fentanyl and propofol to induce anesthesia, then will receive standard rate of fluid maintenance during surgery.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Mandana Jahanian

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Ghaem Hospital, Ahmadabad Street, Dr. Ali Shariati Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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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
Mandana Jahanian
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Not applicable
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
Not applicable
Data Dictionary
Not applicable
Title and more details about the data/document
The research data obtained from the main outcomes of the study can be shared freely as 'open data'.
When the data will become available and for how long
6 months after publishing the results
To whom data/document is available
The research data is exclusively accessible to the researchers working at universities and centers for scientific research.
Under which criteria data/document could be used
The research data is exclusively accessible to the researchers working at universities and centers for scientific research.
From where data/document is obtainable

Mandana Jahanian provides the data analysis to the applicants via email: jahanianm991@mums.ac.ir

What processes are involved for a request to access data/document

Applicants can send emails to him and receive a response within a week.

Comments