Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Nov 2026

Effect of Intravenous Magnesium Sulfate Administration on Reducing Intraoperative Hypoxia in Patients Undergoing Thoracotomy

Protocol summary

Study aim
Primary objective is to assess whether 2 g IV magnesium sulfate reduces hypoxia during OLV in thoracotomy. Secondary objectives include evaluating severity and duration of hypoxia, hemodynamic and $EtCO_2$ changes, and adverse events.

Design
A randomized, double-blind

Settings and conduct
Patients are randomly assigned using sealed envelopes. Study conducted at a university thoracic surgery center.

Participants/Inclusion and exclusion criteria
Inclusion: adults 18–65 undergoing elective thoracotomy with OLV. Exclusion: pregnancy, magnesium allergy, severe cardiac/renal failure.

Intervention groups
Intervention group receives 2 g magnesium sulfate IV after induction; control receives equal volume of normal saline.

Main outcome variables
Primary outcome is incidence of hypoxia ($SpO_2 < 90\%$); secondary outcomes include hemodynamic and $EtCO_2$ changes.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250923067343N4**
Registration date: **2026-06-05, 1405/03/15**
Registration timing: **prospective**

Last update: **2026-06-05, 1405/03/15**
Update count: **0**

Registration date
2026-06-05, 1405/03/15

Registrant information

Name
kobra Rafiei badi

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
2026-06-22, 1405/04/01

Expected recruitment end date
2026-09-22, 1405/06/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Effect of Intravenous Magnesium Sulfate Administration on Reducing Intraoperative Hypoxia in Patients Undergoing Thoracotomy

Public title
Effect of Magnesium Sulfate on Reducing Oxygen Desaturation During Chest Surgery.

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
informed consent Age 18 to 65 years ASA class I–III Candidate for elective thoracotomy Requirement for one-lung ventilation (OLV).

Exclusion criteria:

Severe cardiac or renal failure History of magnesium hypersensitivity Pregnancy Intraoperative termination of surgery or inability to continue OLV due to unexpected causes Need for urgent change in the anesthesia technique

Age
From **18 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description
Method: Block randomization with blocks of four Allocation ratio: 1:1 Software: Random Allocation Software Allocation concealment: Sequentially numbered, opaque, sealed envelopes (SNOSE)

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is designed as a double-blind clinical trial. To maintain blinding, the intervention solution (magnesium sulfate) and the placebo (normal saline) will be prepared by a third party (pharmacist or research nurse) in syringes identical in appearance, volume, and color. All solutions will be administered at the same rate and timing. Group allocation will be performed using a computer-generated random sequence with proper allocation concealment. Throughout the study, the patients, anesthesiologists, surgical team, and outcome assessors will remain unaware of the assigned intervention in order to minimize the risk of bias.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahid Beheshti University of Medical Sciences

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5th Floor, Building No. 2, Shahid Arabi St., Yaman St., Shahid Chamran Hwy., Tehran, Iran.

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Approval date
2026-05-23, 1405/03/02

Ethics committee reference number
IR.SBMU.MSP.REC.1405.123

Health conditions studied

1

Description of health condition studied
The patient undergoing thoracotomy surgery.

ICD-10 code
G54.3

ICD-10 code description
Thoracic root disorders, not elsewhere classified

Primary outcomes

1

Description
Incidence of hypoxia (SpO_2 < 90% ≥ 30 s)

Timepoint
Throughout OLV

Method of measurement
Pulse oximetry

Secondary outcomes

1

Description
Mean SpO_2

Timepoint
Baseline, 15 min OLV, 30 min OLV

Method of measurement
Pulse oximetry

2

Description
mean Etco2

Timepoint
Cnotinuous

Method of measurement
Capnography

3

Description
ContinuousMAP and HR

Timepoint
every 5 minutes

Method of measurement
Standard monitoring

4

Description
Number of hypoxic episodes
Timepoint
During OLV
Method of measurement
Continuous monitoring

Intervention groups

1

Description
In the intervention group, 2 g of intravenous magnesium sulfate diluted in 100 mL of normal saline is administered immediately after anesthesia induction over 15–20 minutes.
Category
Treatment - Drugs

2

Description
Control group: In the control group, 100 mL of normal saline is administered intravenously immediately after anesthesia induction over 15–20 minutes. The appearance, volume, and method of administration are identical to the intervention group to maintain blinding.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Masih Daneshvari Hospital
Full name of responsible person
Kobra Rafiei Badi
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Sponsors / Funding sources

1

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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
Shahid Beheshti 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
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Full name of responsible person
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Position
assistant of professor
Latest degree
Specialist
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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not 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
Not applicable