

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 Jun 2026

### The effect of peri-operative magnesium sulfate infusion on inflammatory factors in patients with lung cancer

#### Protocol summary

##### Study aim

The effect of perioperative magnesium sulfate infusion on inflammatory factors in patients with lung cancer

##### Design

Double-blind, two-arm parallel groups, randomized clinical trial study with the control group. Patients are divided into 2 groups of 22 using random numbers from the online research randomizer service.

##### Settings and conduct

This randomized clinical trial study evaluates 44 patients candidates for lobectomy due to lung cancer, admitted to Imam Khomeini Hospital in Tehran between 2020-2021. Serum levels of WBC, albumin, CRP, and inflammatory (IL-6, IL-8) and anti-inflammatory (IL-10 and TGF-B) cytokines will check twice (immediately after induction and a day after surgery) in two of 22 groups of controls (Standard Protocol on Anesthesia and Surgery) and study (administration of MgSO<sub>4</sub>). Demographic data, mortality rate, and treatment outcome are evaluated in the study groups separately by a questionnaire.

##### Participants/Inclusion and exclusion criteria

Participants: lung cancer patients candidate for lobectomy, pneumonectomy, admitted to Imam Khomeini Hospital in Tehran between 2020-2021. Inclusion criteria: patients with stage I, II lung cancer, aged 18 to 65 years old. Exclusion criteria: history of severe systemic and functional lung diseases, concomitant diagnosed with other cancers, immunodeficiency, acute and chronic renal failure, history of drugs with the hypermagnesemia side effect.

##### Intervention groups

Control group: standard protocol of anesthesia and surgery. Study group: MgSO<sub>4</sub> administration; in addition to standard cares, MgSO<sub>4</sub> is added during induction of anesthesia (40 mg/kg within 10 minutes) and then infusion of maintenance dose until the end of surgery (10 mg/kg/h).

##### Main outcome variables

Primary outcome: evaluation of inflammatory and anti-

inflammatory factors level in the study groups. Secondary outcome: mortality rate and treatment outcome in the study groups.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20120305009213N5**

Registration date: **2022-04-14, 1401/01/25**

Registration timing: **retrospective**

Last update: **2022-04-14, 1401/01/25**

Update count: **0**

##### Registration date

2022-04-14, 1401/01/25

##### Registrant information

##### Name

Jalil Makarem

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6658 1576

##### Email address

j-makarem@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-09-22, 1399/07/01

##### Expected recruitment end date

2021-07-23, 1400/05/01

##### Actual recruitment start date

2020-09-22, 1399/07/01

**Actual recruitment end date**

2022-02-18, 1400/11/29

**Trial completion date**

empty

**Scientific title**

The effect of peri-operative magnesium sulfate infusion on inflammatory factors in patients with lung cancer

**Public title**

Effect of peri-operative magnesium sulfate infusion on inflammatory factors in patients with lung cancer

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with stage I (cT1N0 and cT2N0), stage II (cT1N1, cT2N1 and cT3N0) lung cancer Age 18 to 65 years old Candidate for lobectomy or pneumoectomy surgery Informed consent

**Exclusion criteria:**

History of severe heart disease, severe systemic and functional lung disease (asthma, COPD) Electrolyte disturbance BMI below 16 concurrent history of other cancers Albumin level less than 5.2 stage IIIA (cT3N1 and cT1-3N2) lung cancer and above Small cell carcinoma HIV positive or any immunodeficiency Patients undergoing clinical trial studies at the same time as this study Dissatisfaction with participating in the study Incomplete tumor resection (potential effect on cytokine levels) Long incision on chest wall, diaphragm or mediastinum Prescribing corticosteroids Pulmonary fibrosis (affected IL-8) History of chemotherapy and radiotherapy during the past month Patients with severe chronic renal failure (creatinine clearance less than 30 ml / min) Patients with acute renal failure and anuria Patients treated with drugs that produce hypermagnesemia (such as spironolactone, eplerenone)

**Age**

From **18 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

- Participant
- Data analyser

**Sample size**

Target sample size: **44**

Actual sample size reached: **44**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Patients are randomly divided into 2 groups of 22 using random numbers by the online research randomizer service (randomizer.org).

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients entered the study after obtaining informed consent and receiving pre-operative magnesium sulfate

infusion while receiving anesthesia drugs without telling them. Also, a separate individual from the main researcher will do the statistical analysis and the data of the studied groups are coded and delivered to him without specifying the intervention and control group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

Ethics committee of Imam Khomeini Hospital Complex- Tehran University of Medical Sciences

**Street address**

Ghods st., Keshavarz blvd.

**City**

Tehran

**Province**

Tehran

**Postal code**

1419733141

**Approval date**

2020-09-02, 1399/06/12

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1399.199

**Health conditions studied****1****Description of health condition studied**

Lung cancer

**ICD-10 code**

C34

**ICD-10 code description**

Malignant neoplasm of bronchus and lung

**Primary outcomes****1****Description**

Evaluation of blood levels of inflammatory (IL6, IL8) and anti-inflammatory (IL10, TGF-B) factors in the study groups

**Timepoint**

A blood sample is collected as a control immediately after induction of anesthesia and then another sample one day after surgery.

**Method of measurement**

Using ELISA test

## Secondary outcomes

1

### Description

Mortality rate

### Timepoint

At the time of hospitalization up to 6 months after discharge

### Method of measurement

Questionnaire

## Intervention groups

1

### Description

Control group: Standard protocol of anesthesia and surgery

### Category

Treatment - Drugs

2

### Description

Intervention group: MgSO<sub>4</sub> administration; in addition to standard cares, administration of MgSO<sub>4</sub> made by Karmania Pars gene (KPG) company is added during induction of anesthesia (40 mg/kg within 10 minutes) and then infusion of maintenance dose until the end of surgery (10 mg/kg/h).

### Category

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

#### Name of recruitment center

Imam Komeini Hospital Complex - Valiasr Hospital

#### Full name of responsible person

Mahsa Hamidi

#### Street address

Valiasr Hospital, Imam Khomeini Hospital Complex, End of Keshavarz Blvd.

#### City

Tehran

#### Province

Tehran

#### Postal code

1419733141

#### Phone

+98 21 6119 0008

#### Email

hosp\_valiasr@tums.ac.ir

#### Web page address

<http://medicine.tums.ac.ir/valiasr/>

## Sponsors / Funding sources

1

### Sponsor

#### Name of organization / entity

Cancer institute

#### Full name of responsible person

Mohammad Ali Mohagheghi

#### Street address

Cancer institute, Imam Khomeini Hospital Complex, End of Keshavarz Blvd.

#### City

Tehran

#### Province

Tehran

#### Postal code

14197733141

#### Phone

+98 21 6119 2501

#### Email

crc@tums.ac.ir

#### Web page address

<http://cri.tums.ac.ir/>

### Grant name

### Grant code / Reference number

99-1-115-47836

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

Yes

### Title of funding source

Cancer institute

### 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

Tehran University of Medical Sciences

#### Full name of responsible person

Mahsa Hamidi Adl

#### Position

Anesthesiology Assistant

#### Latest degree

Medical doctor

#### Other areas of specialty/work

Anesthesiology

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#### Postal code

1419733141

**Phone**

+98 21 6119 0008

**Email**

dr.mahsa.hamidi@gmail.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Jalil Makarem

**Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Mahsa Hamidi Adl

**Position**

Anesthesiology Assistant

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

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blvd.

**City**

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**Province**

Tehran

**Postal code**

1419733141

**Phone**

+98 21 6119 0008

**Email**

dr.mahsa.hamidi@gmail.com

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

Yes - There is 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**

Yes - There is a plan to make this available

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

Evaluated data for the primary and secondary outcome

**When the data will become available and for how long**

These data are available for one year after the end of the study (2021-2022)

**To whom data/document is available**

The data will be available only to researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

The use of this data is permitted for any research purpose

**From where data/document is obtainable**

To receive this data, refer to the person responsible for the general inquiries

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

This data will be sent within a week after sending an email to the person responsible for general inquiries of this study via university email, stating personal academic details and the reason and type of data use.

**Comments**