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 MgSO4). 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: MgSO4 administration; in addition to standard cares, MgSO4 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

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Jalil Makarem

Name of organization / entity
Tehran University of Medical Sciences

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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: MgSO4 administration; in addition to standard cares, administration of MgSO4 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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Cancer institute
Full name of responsible person
Mohammad Ali Mohagheghi
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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
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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