Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jun 2026

Determining the effect of venous magnesium on improving the quality of anesthesia in patients undergoing appendectomy under spinal anesthesia

Protocol summary

Study aim
Determining the effect of venous magnesium on improving the quality of anesthesia in patients undergoing appendectomy under spinal anesthesia

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 0 on 84 patients. The randomization of patients into two groups will be in the form of blocks, and for the 84 studied patients, four blocks of different sequences A, B have been prepared with the help of statistical software.

Settings and conduct
This study will be conducted on 84 patients referred to Fatemi Ardabil Hospital with diagnosis of acute appendicitis. The present study is a double-blind clinical trial in which the patient and the evaluator are not aware of the intended intervention For patients in the intervention group, intravenous magnesium sulfate will be used, and in the control group, normal saline will be used as a placebo. Patients will be evaluated using a questionnaire

Participants/Inclusion and exclusion criteria
Entry requirements: age 18 to 50, acute appendicitis patients Conditions of non-entry: history of drug abuse, alcohol consumption, recent use of tranquilizers, sedatives and antipsychotics, antihypertensive drugs, calcium channel blockers, and the existence of neuromuscular diseases, thyroid disorders, kidney and heart disease

Intervention groups
In this study, the patients of the study group were given magnesium sulfate in the amount of 50 mg per kilogram of body weight intravenously before the operation and 8 mg per kilogram during the operation, and the patients of the control group were given an equal volume of isotonic normal saline solution intravenously will receive.

Main outcome variables
Pain, nausea and vomiting, anxiety, satisfaction of the surgeon

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230307057651N1**
Registration date: **2023-05-03, 1402/02/13**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-03, 1402/02/13**
Update count: **0**

Registration date
2023-05-03, 1402/02/13

Registrant information

Name
Mina Deldade Moghaddam

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 45 3325 7086

Email address
d.mina15@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-01, 1402/01/12

Expected recruitment end date
2023-06-02, 1402/03/12

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Determining the effect of venous magnesium on improving the quality of anesthesia in patients undergoing appendectomy under spinal anesthesia

Public title
Determining the effect of venous magnesium on improving the quality of anesthesia
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 50 years, acute appendicitis patients
Exclusion criteria:
History of drug abuse, alcohol consumption, recent use of tranquilizers, stimulants and antipsychotics, antihypertensive drugs, calcium channel blockers, and history of neuromuscular diseases, thyroid disorders, history of any type of kidney and heart disease.
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
0
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **84**
Randomization (investigator's opinion)
Randomized
Randomization description
After entering the study, patients are randomly assigned to two experimental groups (study intervention) and control based on codes A and B.The method of randomly assigning patients to two groups will be in the form of blocks, for the 84 patients studied previously, four blocks of different sequences A, B have been prepared with the help of statistical software, and the random sequences obtained in the form of envelopes containing codes A and B in the package are given to a person who does not know about the drugs used, and after each person enters the study, the corresponding envelope is opened and the person's code is determined, and the corresponding intervention is performed by the anesthesia resident who is not part of the study.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients and the operator will be unaware of the type of medicine.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences
Street address
At the end of University Street, Ardabil University of Medical Sciences administrative complex
City
Ardabil
Province
Ardabil
Postal code
۵۶۱۸۹-۸۵۹۹۱
Approval date
2023-03-03, 1401/12/12
Ethics committee reference number
Ir.ARUMS.REC.1401.236

Health conditions studied

1

Description of health condition studied
Appendicitis
ICD-10 code
K35
ICD-10 code description
Acute appendicitis

2

Description of health condition studied
pain
ICD-10 code
R52
ICD-10 code description
Pain, unspecified

3

Description of health condition studied
nausea and vomiting
ICD-10 code
R11
ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
pain
Timepoint
Pain measurement at 1, 3, 6, 12 and 18 hours after surgery
Method of measurement
The measurement of patients' pain will be based on the

criteria for measuring patients pain with 'Visual Analogue Scale.Zero point is equal to not having any pain and 10 is the most severe possible pain

Secondary outcomes

1

Description
nausea and vomiting
Timepoint
3 and 12 hours after surgery
Method of measurement
Based on a qualitative review by the following method:1- No nausea and vomiting 2- Nausea 3- Nausea and vomiting one to two times 4- Nausea and vomiting more than 2 times

2

Description
Anxiety and restlessness
Timepoint
3, 6, 12, 18 hours after surgery
Method of measurement
According to Ramsey scale (0 to 5): 0 (restless), 1 (calm and alert), 2 (sleepy), 3 (confused but responding to verbal commands), 4 (no response to verbal commands), 5 (absence) response to provocations))

3

Description
Consent of the surgeon
Timepoint
During surgery
Method of measurement
has / does not have

Intervention groups

1

Description
Intervention group: Patients in the intervention group in the study will receive magnesium sulfate at the rate of 50 mg per kilogram of body weight intravenously before the operation and 8 mg per kilogram during the operation.
Category
Treatment - Drugs

2

Description
Control group: Patients in the control group will receive distilled water at the rate of 50 mg per kilogram of body weight intravenously before the operation and 8 mg per kilogram during the operation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Fatemi Hospital
Full name of responsible person
Mina Deldadeh moghaddam
Street address
Emam khomeini
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Ardabil
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5614733775
Phone
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Email
fatemi@arums.ac.ir
Web page address
https://fatemi.arums.ac.ir/fa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
بهمن بشردوست
Street address
At the end of University Street, Ardabil University of Medical Sciences administrative complex
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Email
m_automation@arums.ac.ir
Web page address
https://medicine.arums.ac.ir/fa
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ardabil 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

Ardabil University of Medical Sciences

Full name of responsible person

Mina Deldadeh Moghaddam

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Mahzad yosefiyan

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Full name of responsible person

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Position

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Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available