

# 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

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5614733775

##### Phone

+98 45 3323 2520

##### 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

##### City

Ardabil

##### Province

Ardabil

##### Postal code

5618953141

##### Phone

+98 45 3353 4694

##### 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

**Street address**

No. 1, Molavi St., 8 Molvi

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Ardabil

**Province**

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**Postal code**

5614733775

**Phone**

+98 45 3325 7086

**Email**

d.mina15@yahoo.com

**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Ardabil University of Medical Sciences

**Full name of responsible person**

Mahzad yosefiyan

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Ardabil, Jhanbazan Square, the end of University Street, above University Square , Faculty of Medicine and Paramedicine

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5614733775

**Phone**

+98 45 3323 2520

**Email**

d.mina15@yahoo.com

**Person responsible for updating data**

**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

**Street address**

No. 1, Molavi St., 8 Molvi

**City**

Ardabil

**Province**

Ardabil

**Postal code**

5618953141

**Phone**

+98 45 3325 7086

**Email**

d.mina15@yahoo.com

**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