

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Effect of prophylactic administration of two doses of magnesium sulfate on cardiovascular changes during general anesthesia in Gynecologic laparoscopic surgery compared with women in the placebo group attending

#### Protocol summary

##### Study aim

This study aimed to evaluate the effect of two doses of magnesium sulphate on cardiovascular changes during general anesthesia in laparoscopic surgeries of women.

##### Design

Groups and their number were determined by the anesthetist nurse who did not play a role in study. In the days that me was in hospital and was a woman's laparoscopic surgery, she presented a 50-cc syringe to me for injection that contained either 30 mg magnesium sulfate, 50 or without sulfate. after inject, i write the Symptoms of the patient and then back the form to the nurse for write the dose of sulfate magnesium and archives form.

##### Settings and conduct

The place of the study was Shahid Beheshti Hospital and Alzahra Hospital in Isfahan. Groups and their number were determined by the anesthetist nurse who did not play a role in study. In the days that me was in hospital and was a woman's laparoscopic surgery, she presented a 50-cc syringe to me for injection that contained either 30 mg magnesium sulfate, 50 or without sulfate. after inject, i write the Symptoms of the patient and then back the form to the nurse for write the dose of sulfate magnesium and archives form.

##### Participants/Inclusion and exclusion criteria

Candidate for laparoscopic surgery for women including ASA patients 1 and 2

##### Intervention groups

Patients were divided into three groups of placebo (p): 36; the group receiving 30 mg / kg magnesium sulfate (M1) was 35 and the group receiving 50 mg / kg magnesium sulfate (M2) was divided into 35

##### Main outcome variables

Changes in blood pressure, changes in heart rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190105042236N1**

Registration date: **2019-02-10, 1397/11/21**

Registration timing: **retrospective**

Last update: **2019-02-10, 1397/11/21**

Update count: **0**

##### Registration date

2019-02-10, 1397/11/21

##### Registrant information

##### Name

Mona Mostashfi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 3267 9440

##### Email address

amirmostashfi@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2016-10-22, 1395/08/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

2016-10-22, 1395/08/01

##### Actual recruitment end date

2017-05-20, 1396/02/30

##### Trial completion date

2017-05-20, 1396/02/30

### Scientific title

Effect of prophylactic administration of two doses of magnesium sulfate on cardiovascular changes during general anesthesia in Gynecologic laparoscopic surgery compared with women in the placebo group attending

### Public title

Effect of prophylactic administration of magnesium sulfate on cardiovascular changes during general anesthesia in Gynecologic laparoscopic surgery

### Purpose

Supportive

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients ASA 1 Patients ASA 2 Women Laparoscopic Surgery Outer uterus and endometriosis and diagnosis (infertility) Maximum operating time is 150 minutes

#### Exclusion criteria:

High blood pressure Sensitization to magnesium sulfate Heart block Emergency situation

### Age

No age limit

### Gender

Female

### Phase

2-3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

### Sample size

Target sample size: **100**

Actual sample size reached: **106**

### Randomization (investigator's opinion)

Randomized

### Randomization description

This study was performed on patients who underwent surgery in Shahid Beheshti and Alzahra Hospitals in Isfahan during the study days as a simple randomized method. So that the syringes of the drug studied by the anesthetist nurse who did not play a role in the data were filled up during the study of the performed surgical operations with a volume of 50 cc (This 50 cc contain 30 cc dose of sulfate or contain 50 cc dose of sulfate or neutral and there was a dose that the injector who was a slave or someone else did not know about this agent)

### Blinding (investigator's opinion)

Double blinded

### Blinding description

This study was performed on patients who underwent surgery in Shahid Beheshti and Alzahra Hospitals in Isfahan during the study days as a simple randomized method. So that the syringes of the drug studied by the anesthetist nurse who did not play a role in the data were filled up during the study of the performed surgical operations with a volume of 50 cc (This 50 cc contain 30 cc dose of sulfate or contain 50 cc dose of sulfate or neutral and there was a dose that the injector who was a

slave or someone else did not know about this agent)

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Isfahan Medical School

##### Street address

Alzahra Hospital, Sofeh Blvd, Isfahan Province, Isfahan

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174675731

#### Approval date

2016-04-17, 1395/01/29

#### Ethics committee reference number

396140

## Health conditions studied

### 1

#### Description of health condition studied

Effect of prophylactic administration of two doses of magnesium sulfate on cardiovascular changes during general anesthesia in Gynecologic laparoscopic surgery

#### ICD-10 code

E61.2

#### ICD-10 code description

Magnesium deficiency

## Primary outcomes

### 1

#### Description

Change of systolic blood pressure

#### Timepoint

before the induction of anesthesia as a base and after the anesthesia were measured and recorded after the finishing of the infused medication. These parameters were measured and recorded immediately before the pneumoperitoneum and 5, 10, 20, 30, 40 minutes After pneumoperitoneum.

#### Method of measurement

Barometer

## 2

### **Description**

Change of heart rate

### **Timepoint**

before the induction of anesthesia as a base and after the anesthesia were measured and recorded after the finishing of the infused medication. These parameters were measured and recorded immediately before the pneumoperitoneum and 5, 10, 20, 30,40 minutes After pneumoperitoneum.

### **Method of measurement**

Pulse oximeter

## **Secondary outcomes**

### 1

### **Description**

The amount of chills and vomiting

### **Timepoint**

After the recovery

### **Method of measurement**

Objective observation and question

## **Intervention groups**

### 1

### **Description**

Intervention group: Magnesium sulfate at a dose of 30 mg / kg

### **Category**

Prevention

### 2

### **Description**

Intervention group: Magnesium sulfate at a dose of 50 mg / kg

### **Category**

Prevention

### 3

### **Description**

Control group: Without getting magnesium sulfat

### **Category**

Prevention

## **Recruitment centers**

### 1

### **Recruitment center**

#### **Name of recruitment center**

Shahid Beheshti Hospital

#### **Full name of responsible person**

Dr. Anahita Hirman Pour

#### **Street address**

Shahid Beheshti Hospital, Motahari Ave, Isfahan Province, Esfahan

### **City**

Isfahan

### **Province**

Isfahan

### **Postal code**

8174673461

### **Phone**

+98 31 3236 7001

### **Email**

Shahidbeheshti@mui.ac.ir

### 2

### **Recruitment center**

#### **Name of recruitment center**

Alzahra Hospital

#### **Full name of responsible person**

Dr. Anahita Hirman Pour

#### **Street address**

Alzahra Hospital, Sofeh Blvd, Isfahan.

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#### **Province**

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#### **Postal code**

8174675731

#### **Phone**

+98 31 3620 2020

#### **Email**

alzahra@mui.ac.ir

## **Sponsors / Funding sources**

### 1

### **Sponsor**

#### **Name of organization / entity**

Esfahan University of Medical Sciences

#### **Full name of responsible person**

Dr. Hagh Javi

#### **Street address**

Alzahra Hospital, Sofeh Blvd, Isfahan Province, Isfahan

#### **City**

Isfahan

#### **Province**

Isfahan

#### **Postal code**

8174673461

#### **Phone**

+98 31 3668 8138

#### **Email**

sh\_haghjoo@med.mui.ac.ir

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Esfahan 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**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mona Mostashfi

**Position**

Assistant Student of Anesthesiology and Special Care

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

No.15, Keihan ALye, Bisim Ave, Isfahan

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**Fax****Email**

amirmostashfi@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Person responsible for updating data****Contact****Name of organization / entity**

Esfahan University of Medical Sciences

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**Phone**

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**Fax****Email**

amirmostashfi@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**

No - There is not a plan to make this available

**Data Dictionary**

Yes - There is a plan to make this available

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

All personal information can be provided after the name is deleted

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

Start access after posting the related article after 1398

**To whom data/document is available**

Researchers working in academia and academia

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

To develop this study

**From where data/document is obtainable**

Email me. m43.mostashfi@gmail.com

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

Data is provided after examining the individual's request and ensuring proper use and insertion of the data source

## Comments