

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 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.

City

Isfahan

Province

Isfahan

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

City

Isfahan

Province

Isfahan

Postal code

8157764863

Phone

+98 31 3267 9440

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

Full name of responsible person

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Position

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Phone

+98 31 3267 9440

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