

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jul 2026

Comparison of two different doses of Magnesium Sulfate on the prevention of pain during Etomidate injection

Protocol summary

Study aim

Comparison of two different doses of Magnesium Sulfate on prevention of pain during Etomidate injection

Design

The clinical trial includes three groups, has a control group, three-way blinded, randomized, phase 3. It is used for randomizing from Random Allocation Software on 90 sick.

Settings and conduct

This thrple blind clinical trial study is conducted during 2022-2023 in Al-Zahra Hospital of Isfahan. 90 patients who are candidates for anesthesia with Etomidate are randomly divided into three groups. The groups are respectively received 0.750 mg of magnesium sulfate, 1 gram of magnesium sulfate and lidocaine, and the pain during the injection of Etomidate is evaluated and compared between the three groups. In this study, the patients, the researcher and the outcome assessor are blinded.

Participants/Inclusion and exclusion criteria

In this study, patients who are candidates for elective surgery who are candidates for anesthesia with etomidate and have no history of cardiovascular and neuromuscular diseases, pregnancy and liver and kidney diseases are included in the study.

Intervention groups

Intervention group 1: patients receiving 750 mg magnesium sulfate injection
Intervention group 2: patients receiving 1 gram of magnesium sulfate injection
Control group: patients under lidocaine injection

Main outcome variables

Determining og effective dose of magnesium sulfate for prevent pain caused by atomiditis injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090129001615N6**

Registration date: **2023-02-21, 1401/12/02**

Registration timing: **prospective**

Last update: **2023-02-21, 1401/12/02**

Update count: **0**

Registration date

2023-02-21, 1401/12/02

Registrant information

Name

Azim Honarmand

Name of organization / entity

Alzahra hospital

Country

Iran (Islamic Republic of)

Phone

+98 31 3668 0048

Email address

honarmand@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-09-11, 1402/06/20

Expected recruitment end date

2023-09-23, 1402/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two different doses of Magnesium Sulfate on the prevention of pain during Etomidate injection

Public title

The effect of two different doses of Magnesium Sulfate on prevention of pain during Etomidate injection

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

1. All patients who need to anesthesia With Etomidate Aged 18-65 years with ASA (American Society of Anesthesiologists) grade:1 or 2 2. No History of allergy to Magnesium 3. candidate for Elective Surgery

Exclusion criteria:

1. Patients with neuromuscular disease 2. Patients who have Difficulty Communicating 3. Myocardial Ischemia 4. Cardiac Arrhythmia 5. Seizure 6. Endocrine and Metabolic Diseases 7. Mental Disorders 8. Severe Neurological Disease 9. People without a vein in the back of the hand 10. Pregnancy 11. Liver and kidney diseases 12. Thrombophlebitis 13. Chronic pain 14. pancreatic disorders 15. Patients receiving sedative or analgesic drugs 16. Substance abusers

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Because sample volume is low and we want to figure on the balance of the number of people in each group ,We use the permuted(block) randomization method what one of types of restricted randomization method is . In this order that has been made of 15 block s of 6 consisting on 2 numbers out of 2, A numbers out of B and 2 numbers out of C.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding is done as follows: the study drugs are named by the nurse as A and B codes. Patients, researchers and data collectors are unaware of the study group. The studied drugs are injected with the same syringes in terms of volume and color, and therefore the patients will not have any information about the injected drugs.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Esfahan University of Medical Sciences

Street address

Soffeh street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2022-05-15, 1401/02/25

Ethics committee reference number

IR.MUI.MED.REC.1401.058

Health conditions studied

1

Description of health condition studied

Pain due to Etomidate injection

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain intensity during Etomidate injection

Timepoint

Every minute until 10 minutes after Etomidate injecting

Method of measurement

Pain intensity is evaluated with using a 4-point Likert scale including: 0=no pain, 1=mild (pain expressed in response to the patient's question and without symptoms), 2=moderate (pain expressed in response to the patient's question) can be expressed along with the symptoms of the disease or pain spontaneously without asking the patient), 3=severe (a strong facial response or a response accompanied by arm withdrawal or facial grimacing) is measured.

Secondary outcomes

1

Description

Blood pressure

Timepoint

Every minute after Etomidate injection up to 10 minutes

Method of measurement

Pulse oximeter

2

Description

Heart rate

Timepoint

Every minute after Etomidate injection up to 10 minutes

Method of measurement

Pulse oximeter

Intervention groups

1

Description

Intervention group 1: injection of 750 mg of magnesium sulfate 30 seconds before the injection of etomidate

Category

Prevention

2

Description

Intervention group 2: injection of 1 gram of magnesium sulfate 30 seconds before the injection of etomidate

Category

Prevention

3

Description

Control group: injection of 1 mg of lidocaine

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra hospital

Full name of responsible person

Azim Honarmand

Street address

Soffeh street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 5555

Email

honarmand@med.mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Hezarjerib Ave.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Email

gh_askari@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

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Soffeh street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Fax

+98 31 1236 1594

Email

honarmand@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Soffeh street

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 0048

Fax

+98 31 1236 1594

Email

honarmand@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Soffeh street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3668 0048

Fax

+98 31 1236 1594

Email

honarmand@med.mui.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

The plan belongs to the government organization and it is not possible to share it.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available