

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the effect of magnesium sulfate and lidocaine spray on hemodynamic changes due to laryngoscopy and Tracheal intubation - Clinical trial

Protocol summary

Study aim

Comparison of magnesium and lidocaine sulfate spray on hemodynamic changes induced by laryngoscopy

Design

Clinical trial with control group, with parallel, double-blind, randomized, phase 2 on 100 patients. For randomization, the rand function of Excel software was used.

Settings and conduct

This study is a double-blind clinical trial and 100 patients aged 18 to 40 years old (in two groups of 50 people) who have no underlying disease and are candidates for elective orthopedic surgery and general surgery, will be studied in Karaj Madani Hospital. Double-blind study means that the person who records vital signs after laryngoscopy and the person who analyzes the statistical results does not know about the two groups A and B and what spray was used in each group.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients aged 18 to 40 years old who are in ASA (American Society Anesthesiology) Class I,II. BMI is in the range of 19 to 25. Have a mallampaty score of one or two Exclusion criteria: 1. Patient dissatisfaction or withdrawal from participation in the study 2. Having sensitivity to magnesium sulfate and lidocaine 3. Being a smoker

Intervention groups

Intervention group are candidates for elective orthopedic surgery and general surgery who receive magnesium sulfate spray Comparison group is candidate for elective orthopedic surgery and general surgery who receive lidocaine spray

Main outcome variables

Determination of heart rate and blood pressure and ECG changes

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230719058846N1**

Registration date: **2023-10-31, 1402/08/09**

Registration timing: **prospective**

Last update: **2023-10-31, 1402/08/09**

Update count: **0**

Registration date

2023-10-31, 1402/08/09

Registrant information

Name

Marziye Khalaji

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4460 9281

Email address

mingming501.n1@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-21, 1402/08/30

Expected recruitment end date

2023-12-21, 1402/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of magnesium sulfate and lidocaine spray on hemodynamic changes due to laryngoscopy and Tracheal intubation - Clinical trial

Public title

Comparison of magnesium sulfate and lidocaine spray on hemodynamic changes due to laryngoscopy

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

All patients aged 18 to 40 years old who are in ASA (American Society Anesthesiology) Class I,II. BMI is in the range of 19 to 25 Have a mallampaty score of one or two

Exclusion criteria:

1. Patient dissatisfaction or withdrawal from participation in the study 2. Having sensitivity to magnesium sulfate and lidocaine 3. Being a smoker 4. Having a cold, cough and sputum 5. Have a mallampaty score of three or four 6. In terms of airway examination in the Lemon Law criteria have problem of intubation and diffusion should have. 7. If the laryngoscopy lasts longer than 15 seconds. If there is a problem during laryngoscopy and the patient has a difficult intubation. 8. Having a history of arterial hypertension, tachycardia, bradycardia and arrhythmia 9. Use of hemodynamic drugs such as indral and ...

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Random Method : Simple Randomization Unit : Individual Randomization Tool : Using random cards A and B 50 cards A and 50 cards B that have the same appearance are placed in a container without the letters in the card being visible from outside. The study subjects take a card from the inside of the container and are classified into lidocaine or magnesium sulfate depending on the selected card. The selection of the card is permutation free and the card removed will not be placed in the container again. The study subjects will not know the letters in the cards and which of the drugs they are studying. Also, the subjects in the study will not be related to each other.

Blinding (investigator's opinion)

Double blinded

Blinding description

The sprays are uniformed and covered in appearance, and the performer, who is the executor of the project,

and the person recording the results do not know about the substance inside them.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

No. 5, West 3rd Alley, 12 meters of Boostan St, Danesh St, Central Jannatabad, Tehran, Iran

City

tehran

Province

Tehran

Postal code

1475643684

Approval date

2023-06-09, 1402/03/19

Ethics committee reference number

IR.ABZUMS.REC.1402.086

Health conditions studied

1

Description of health condition studied

Hemodynamic changes including heart rate and blood pressure and ECG changes after laryngoscopy

ICD-10 code

I97.8

ICD-10 code description

Other intraoperative and postprocedural complications and disorders of the circulatory system, not elsewhere classified

Primary outcomes

1

Description

Systolic and diastolic blood pressure

Timepoint

Minutes 1, 3, 5, 7 and 10 from the start of the intervention.

Method of measurement

Operating Room Pressure Gauge

2

Description

heart rate

Timepoint

Minutes 1, 3, 5, 7 and 10 from the start of the intervention.

Method of measurement

Heart Rate Indicator Device in Operating Room

Secondary outcomes

1

Description

changes in ECG

Timepoint

Minutes 1, 3, 5, 7 and 10 from the start of the intervention.

Method of measurement

Electrocardiogram Monitor

Intervention groups

1

Description

Intervention group: In one of the studied patients, 5 puffs of lidocaine 10% containing 10 mg of lidocaine is sprayed in the throat. In the next step for both groups of atracurium relaxant 0.75 mg/kg and after 3 minutes the patient will be laryngoscopy and intubation (intubation is done by expert and maximum within 15 seconds and for men tube eight and for women pipe seven with Macintosh laryngoscope blade 4 will be used after laryngoscopy to measure changes in heart rate and blood pressure and ECG changes in minutes 1, 3, 5, 7 and 10

Category

Treatment - Drugs

2

Description

Intervention group: In one group of patients, 5 puffs of magnesium sulfate spray 20% in the enclave. In the next step for both groups of atrophorium relaxant 0.75 mg/kg and after 3 minutes the patient will be laryngoscopy and intubation (intubation is done by expert and maximum within 15 seconds and for men tube eight and for women tube seven with blade laryngoscope macintosh 4 After laryngoscopy, we measure and record changes in heart rate and blood pressure and ECG changes in minutes 1, 3, 5, 7 and 10.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Madani Hospital of Karaj

Full name of responsible person

Dr.Banafsheh Mashak

Street address

Shahid Madani Square, Mahan Blvd, Taleghani Crossroads, Karaj, Iran

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karaj

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Alborz

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Phone

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Fax

Email

Madani.hospital@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr.Banafshe Mashak

Street address

Deputy of Research and Technology - Saffarian Alley - 45 meters Golshahr - Karaj

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karaj

Province

Alborz

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3198764653

Phone

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Research@abzums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Karaj 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

Karaj University of Medical Sciences

Full name of responsible person

Dr.Banafsheh Mashak

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Kamali Medical Center, Kamali St., Shohada Sq.,
Shahid Beheshti St., Karaj Province, Iran

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr.Banafsheh Mashak

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Email

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Person responsible for updating data

Contact

Name of organization / entity

Karaj University of Medical Sciences

Full name of responsible person

Dr.Banafsheh Mashak

Position

Assistant Professor

Latest degree

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Other areas of specialty/work

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Email

mashakbanafsheh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is 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

Title and more details about the data/document

The whole data is potentially shareable after making people unidentifiable.

When the data will become available and for how long

Beginning of access period 6 months after publication of results

To whom data/document is available

Researchers working in academic and scientific institutions and people working in industry

Under which criteria data/document could be used

For other scientific and research studies Dastva Studies and Measures Use in medical centers

From where data/document is obtainable

Executor of Dr. Khalaji with Email Address
mar_k98@yahoo.com

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

Send an email to the project's executor Introducing the requesting person and organization Explanation of the

purpose of the individual or organization of access to

information
Comments