

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

Comparison of magnesium sulfate and dexmedetomidine and ondansetron supplementation with lidocaine for pre-laryngoscopic and tracheal intubation gargling in prevention of sore throat and control of hemodynamic changes

Protocol summary

Study aim

Comparison of magnesium sulfate and dexmedetomidine and ondansetron supplementation with lidocaine for pre-laryngoscopic and tracheal intubation gargling in prevention of sore throat and control of hemodynamic changes

Design

The study of the two-course clinical trial of 105 patients was randomly divided into 4 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients with general anesthesia at Valiasr hospital in Arak are divided into 3 groups by simple randomization with envelopes. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 30 to 60 years, ASA class 1 and 2, No history of sore throat before surgery, No history of head and neck surgery, especially of the throat, No history of drug use, No history of chronic housing use, Lack of sensitivity to the drugs used in this study, Lack of upper airway infection and cold, Malampati more than 2, Lack of liver and kidney failure, No need to use NG-tube during surgery and up to 24 hours after surgery, The duration of surgery should not be less than 45 minutes and not more than 120 minutes Exclusion criteria: Patient dissatisfaction with continuing to study, observation of blood during suction when removing the tracheal tube, for whatever reason, we have to have laryngoscopy twice

Intervention groups

Intervention group 1: Patients will get 2 gram Magnesium Sulfate 20 percent (Shahid ghazi Co) plus 100 milligram Lidocaine and 5 millilitre Dextrose 20 percent. Intervention group 2: Patients will get 1

microgram Dexmedetomidine (Exir Co) plus 100 milligram Lidocaine and 5 millilitre Dextrose 20 percent. Intervention group 3: Patients will get 4 milligram Ondansetron (Exir Co) plus 100 milligram Lidocaine and 5 millilitre Dextrose 20 percent.

Main outcome variables

Cough, hoarseness, sore throat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N145**

Registration date: **2020-07-05, 1399/04/15**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-05, 1399/04/15**

Update count: **0**

Registration date

2020-07-05, 1399/04/15

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2021-04-19, 1400/01/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of magnesium sulfate and dexmedetomidine and ondansetron supplementation with lidocaine for pre-laryngoscopic and tracheal intubation gargling in prevention of sore throat and control of hemodynamic changes

Public title

Comparison of magnesium sulfate and dexmedetomidine and ondansetron supplementation with lidocaine for pre-laryngoscopic and tracheal intubation gargling in prevention of sore throat and control of hemodynamic changes

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

30 to 60 years ASA class 1 and 2 No history of sore throat before surgery No history of head and neck surgery, especially of the throat No history of drug use No history of chronic housing use Lack of sensitivity to the drugs used in this study Lack of upper airway infection and cold Malampati more than 2 Lack of liver and kidney failure No need to use NG-tube during surgery and up to 24 hours after surgery The duration of surgery should not be less than 45 minutes and not more than 120 minutes

Exclusion criteria:

Patient dissatisfaction with continuing to study Observation of blood during suction when removing the tracheal tube For whatever reason, we have to have laryngoscopy twice

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in 3 groups A and B and C . In this method, we

write a few cards or letters as intervention groups and the same number of cards for the control group, then the cards are mixed. One card is taken out and its allocation is registered and the card is returned to the other cards after leaving. Then the cards are mixed again and then another card is picked up. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Outcome evaluator and analyzer and participant are blind. Outcome evaluator and analyzer and participant don't aware from grouping. Drug sets will be covered with foil. After calculating the amount and prescribed at the desired dose.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2020-05-17, 1399/02/28

Ethics committee reference number

IR.ARAKMU.REC.1399.072

Health conditions studied**1****Description of health condition studied**

Sore throat

ICD-10 code

J02.9

ICD-10 code description

Acute pharyngitis, unspecified

Primary outcomes**1****Description**

Sore throat
Timepoint
In recovery and 2, 4, 8, 12 and 24 hours after surgery
Method of measurement
Observation

2

Description
hoarseness
Timepoint
In recovery and 2, 4, 8, 12 and 24 hours after surgery
Method of measurement
Observation

3

Description
Cough
Timepoint
In recovery and 2, 4, 8, 12 and 24 hours after surgery
Method of measurement
Observation

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will grunt 2 gram Magnesium Sulfate 20 percent (Shahid ghazi Co) plus 100 milligram Lidocaine and 5 millilitre Dextrose 20 percent.
Category
Treatment - Drugs

2

Description
Intervention group: atients will grunt 1 microgram Dexmedetomidine (Exir Co) plus 100 milligram Lidocaine and 5 millilitre Dextrose 20 percent. Intervention group
Category
Treatment - Drugs

3

Description
Intervention group: Patients will grunt 4 milligram Ondansetron (Exir Co) plus 100 milligram Lidocaine and 5 millilitre Dextrose 20 percent.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr hospital
Full name of responsible person
Dr Hesamodin Modir
Street address
Valiasr hospital, Valiasr squire
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Email
modir.he@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
alikamaliir@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Shirin Pazuki

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

pazuki@arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamedin Modir

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Email

modir.he@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Erfaneh Abedzadeh

Position

Medicine student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Vice Chancellor for Research and Technology;
Payambar Azam complex, Basij square; Sardasht

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

modir.he@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

Yes - There is 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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Hesamodin Modir

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

They have to write letters to the professors and the university.

Comments