# 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 grunt 2 gram Magnesium Sulfate 20 percent (Shahid ghazi Co) plus 100 milligram Lidocaine and 5 millilitre Dextrose 20 percent. Intervention group 2:Patients will grunt 1 microgram Dexmedetomidine (Exir Co) plus 100 milligram Lidocaine and 5 millilitre Dextrose 20 percent. Intervention group 3:Patients will grunt 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)

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+98 86 3222 2003

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**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 elevator and analyzer and participant are blind. Outcome elevator 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 comittee of Arak University of Medical Sciences
**Street address**
Ethics comittee, Research center, Payambar Azam complex, Basij squre ,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 squre

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Alireza Kamali

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Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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**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
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Anesthesiology
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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Erfaneh Abedzadeh
**Position**
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**Latest degree**
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**Other areas of specialty/work**
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## 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**