

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### A Comparative study of the preoperative effects of Rosemary gargle versus Lidocaine gargle on sore throat and voice violence after endotracheal intubation under general anesthesia in candidates patients for surgeries

#### Protocol summary

##### Study aim

We want to assess the effect of Rosemary gargle versus Lidocaine gargle to find a prophylactic treatment that has high effect on sore throat and voice violence after intubation and also has less side effect

##### Design

Randomized, triple blind clinical trial with 1 control group and 2 intervention groups and phase 3 study of 90 patients. We use Random allocation app to randomize the study.

##### Settings and conduct

Before intubation and preemptively, in group1 we will give gargle of 30 drops of Rosemary solution 5% (Aboureihan company) which will be diluted with 30 drops of distilled water with surgical mesh 2-3 minutes before general anesthesia, In group2 we will give gargle of Lidocaine solution 2% (with dose of 1mg/kg) which will be diluted with 30 drops of distilled water with surgical mesh 2-3 minutes before general anesthesia. In group3 we will give gargle of 30 drops of distilled water with surgical mesh 2-3 minutes before general anesthesia. Research place : Hospitals of Isfahan university of medical sciences (Alzahra and Kashani hospitals).

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate patients for surgery; ASA 1,2; age between 18 to 65 years old; informed consent of patient. Non -inclusion criteria: IV or opioid addicts; previous allergy to this research,s drugs; Heart, Renal or Hepatic failure patients; hard intubation (Grade 4 or upper); malformation of airway tract.

##### Intervention groups

We have 3 intervention groups. In group 1 we will administer Rosemary gargle; group 2 Lidocaine gragle and group 3: distilled water gargle.

##### Main outcome variables

Voice violence; sore throat

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101211005362N29**

Registration date: **2022-02-26, 1400/12/07**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-02-26, 1400/12/07**

Update count: **0**

##### Registration date

2022-02-26, 1400/12/07

##### Registrant information

##### Name

Mohammadreza Safavi

##### Name of organization / entity

Anesthesiology and Critical Care Research Center,  
Isfahan University of Medical Sciences, Isfahan

##### Country

Iran (Islamic Republic of)

##### Phone

+98 31 1273 2659

##### Email address

safavi@med.mui.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-02-20, 1400/12/01

##### Expected recruitment end date

2022-07-23, 1401/05/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**  
empty

**Scientific title**  
A Comparative study of the preoperative effects of Rosemary gargle versus Lidocaine gargle on sore throat and voice violence after endotracheal intubation under general anesthesia in candidates patients for surgeries

**Public title**  
Comparison between Rosemary gargle versus Lidocaine gargle on sore throat and voice violence after endotracheal intubation under general anesthesia in candidates patients for surgeries

**Purpose**  
Prevention

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Candidate patient for surgery ASA 1,2 Age between 18 to 65 years old Informed consent of patient  
**Exclusion criteria:**  
IV or Opioid drugs addicts Previous Allergy to drugs (Rosemary,Lidocaine) Patients with Heart, Renal pr Hepatic failure Hard Intubation (Grade 4 or upper) Malformation of airway tract

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

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Data analyzer

**Sample size**  
Target sample size: **90**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Sampling method will be simple random allocation. Simple random allocation is the easiest and most basic approach that provides unpredictability of treatment assignment. In simple random allocation, treatment assignment is made by chance without regard to prior allocation. For randomization we enter all of samples that have entrance criteria and also not have non-entrance criteria until the volume of samples will be completed. Then we will use the app to randomize them into 3 groups completely randomized. Unit of randomization is group of persons. The tool of randomization will be Random allocation App. That will make sequences based on special programming.

**Blinding (investigator's opinion)**  
Triple blinded

**Blinding description**  
In this research patients, intervention physician and data analyzer do not have any information about groups and using drugs and also their own method. Data will be

analyzed without notice to any of persons above. Only the main performer has information about groups and each one using drugs.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezar Jerib street, Azadi square

##### City

Isfahan

##### Province

Isfahan

##### Postal code

8174673461

#### Approval date

2021-11-04, 1400/08/13

#### Ethics committee reference number

IR.MUI.MED.REC.1400.621

## Health conditions studied

### 1

#### Description of health condition studied

Sore throat

#### ICD-10 code

R07.0

#### ICD-10 code description

Pain in throat

### 2

#### Description of health condition studied

Hoarseness

#### ICD-10 code

R49

#### ICD-10 code description

Voice and resonance disorders

## Primary outcomes

### 1

#### Description

Intensity of sore throat based on VAS scale

#### Timepoint

Every 15 minutes at recovery, every 2 hours in first 6

hour and then at 12 and 24 hours after operation

**Method of measurement**

Visual Analogue Scale

**2**

**Description**

Intensity of voice violence

**Timepoint**

Every 15 minutes at recovery, every 2 hours in first 6 hour and then at 12 and 24 hours after operation

**Method of measurement**

Grade, Roughness, Breathiness, Asthenia, Strain Scale (voice disorder assessment)

**Secondary outcomes**

**1**

**Description**

Average satisfaction level of patients

**Timepoint**

First 48 hours after operation

**Method of measurement**

Hours count that will be measured by researcher.

**2**

**Description**

Average of first time liquids regime toleration

**Timepoint**

First 48 hours after operation

**Method of measurement**

Hours count that will be measured by researcher.

**3**

**Description**

Average of first time solids regime toleration

**Timepoint**

First 48 hours after operation

**Method of measurement**

Hours count that will be measured by researcher.

**Intervention groups**

**1**

**Description**

Intervention group: In group1 we will give gargle of 30 drops of Rosemary solution 5% (Aboureihan company) which will be diluted with 30 drops of distilled water 2-3 minutes before general anesthesia.

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: In group2 we will give gargle of Lidocaine solution 2% (with dose of 1mg/kg) which will be diluted with 30 drops of distilled water 2-3 minutes

before general anesthesia.

**Category**

Treatment - Drugs

**3**

**Description**

Control group: In this group we will give gargle of 30 drops of distilled water 2-3 minutes with surgical mesh before general anesthesia.

**Category**

Treatment - Drugs

**Recruitment centers**

**1**

**Recruitment center**

**Name of recruitment center**

Alzahra hospital

**Full name of responsible person**

Dr. Mohammadreza Safavi Homami

**Street address**

Soffe blvd., Kharrazi highway

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**2**

**Recruitment center**

**Name of recruitment center**

Kashani hospital

**Full name of responsible person**

Dr. Mohammadreza Safavi Homami

**Street address**

Kharrazi highway, Beheshti blvd, Kashani street

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## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Dr. Mansoor Siavash Dastjerdi

**Street address**

Hezar Jerib street, Azadi square

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research@mui.ac.ir

**Web page address**

**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**

Dr. Mohammadreza Safavi Homami

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

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**Latest degree**

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## Person responsible for updating data

### Contact

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**Full name of responsible person**

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**Position**

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**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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## **Sharing plan**

### **Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

### **Study Protocol**

No - There is not 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