

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Evaluation of the effect of dextromethorphan gargling on postoperative quality of recovery and analgesia after endo ultrasonography procedure in scopy ward

#### Protocol summary

##### Study aim

Evaluation of the effect of dextromethorphan gargling on postoperative quality of recovery and analgesia after endo ultrasonography procedure in scopy ward

##### Design

Clinical trial with control group, single-blind, randomized, phase 2 on 60 patients. Randomizer software was used for randomization.

##### Settings and conduct

Candidate patients for endosonography admitted to the scopy ward of Imam Reza Hospital are included in the study and are divided into two groups. The first group gargle dextromethorphan, the second group are sprayed lidocaine into their throats. The researcher and statistical analyzer did not notice the study groups. Finally, the information is evaluated for improvement in recovery and reduction of pain.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for endosonography, age 188 to 65 years, ASA groups 1 and 2 Exclusion criteria: Cardiovascular disease, history of depression, pregnant women

##### Intervention groups

Patients are divided into two groups. The first group gargle dextromethorphan, the second group are sprayed lidocaine into their throats.

##### Main outcome variables

Recovery quality; Pain reduce

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200612047740N5**

Registration date: **2022-06-23, 1401/04/02**

Registration timing: **prospective**

Last update: **2022-06-23, 1401/04/02**

Update count: **0**

##### Registration date

2022-06-23, 1401/04/02

##### Registrant information

###### Name

Hossein Naderi

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 3568 5233

###### Email address

hossein.naderi1374@gmail.com

##### Recruitment status

###### Recruitment complete

##### Funding source

##### Expected recruitment start date

2022-07-22, 1401/04/31

##### Expected recruitment end date

2022-11-20, 1401/08/29

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Evaluation of the effect of dextromethorphan gargling on postoperative quality of recovery and analgesia after endo ultrasonography procedure in scopy ward

##### Public title

The effect of dextromethorphan gargling on improving the quality of recovery after endosonography

##### Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Candidate patients for endosonography ASA 1 AND 2 Age 18 to 65 years

### Exclusion criteria:

Cardiovascular disease History of depression Pregnant women Addiction

## Age

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

## Gender

Both

## Phase

N/A

## Groups that have been masked

- Investigator
- Data analyser

## Sample size

Target sample size: **30**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are randomly assigned to the groups of A and B using Randomization software (<https://www.randomizer.org/>) according to inclusion criteria. Each group has 30 members. In this software, numbers from 1 to 60 are entered into the software and at one time, they randomly pick the numbers from 1 to 60 so that the number of people in each group is equal. The numbers remain hidden and the order in which people enter the study is revealed in the order in which the data output software is displayed, and if the number is between 1 and 30, it is placed in the first group and if it is between 31 and 60, it is placed in the second group.

## Blinding (investigator's opinion)

Single blinded

## Blinding description

Patients are divided into two groups A and B and are kept in two separate parts. How to do the study for each group is described. The information is collected by the clinical caregiver and the researcher and data analyzer do not know the patient group and after analyzing the data, the codes are decoded to avoid bias.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of AJA University of Medical

## Street address

AJA university of medical sciences, Shahid Etemadzade st, West Fatemi st

## City

Tehran

## Province

Tehran

## Postal code

1411718541

## Approval date

2022-06-19, 1401/03/29

## Ethics committee reference number

IR.AJAUMS.REC.1401.020

## Health conditions studied

### 1

#### Description of health condition studied

Pain after endosonography

#### ICD-10 code

G89.18

#### ICD-10 code description

Other acute postprocedural pain

## Primary outcomes

### 1

#### Description

Severity of sore throat

#### Timepoint

After transfer to recovery

#### Method of measurement

visual analogue scale

### 2

#### Description

Satisfaction of operation

#### Timepoint

After transfer to recovery

#### Method of measurement

Numeric Pain Rating Scale

### 3

#### Description

Pain free period

#### Timepoint

From the time a person enters recovery to the time they feel pain in the throat

#### Method of measurement

Ask and record

## Secondary outcomes

### 1

#### Description

Frequency of nausea and vomiting

#### Timepoint

After transfer to recovery

#### Method of measurement

View and record

## 2

#### Description

Frequency of cough

#### Timepoint

After transfer to recovery

#### Method of measurement

View and record

## Intervention groups

### 1

#### Description

Intervention group: Patients gargle dextromethorphan for one minute before endoscopy and endoscopy is performed for them. After finishing the work and transferring them to recovery, the quality of recovery and the amount of sore throat are evaluated.

#### Category

Prevention

### 2

#### Description

Control group: Patients are sprayed 3 puffs of lidocaine on the back of their throats before endoscopy, then endoscopy is performed for them. After finishing the work and transferring them to recovery, the quality of recovery and the amount of sore throat are evaluated.

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Reza hospital

##### Full name of responsible person

Mohammadreza Rafiee

##### Street address

Shahid Etemadzade st, West Fatemi

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##### Email

hossein.naderi1374@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Artesh University of Medical Sciences

##### Full name of responsible person

Dr Mojtaba Yousefi

##### Street address

Shahid Etemadzade st, West Fatemi st

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##### Phone

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##### Email

research@ajaums.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Artesh 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

Hossein Naderi

##### Position

Medical student

##### Latest degree

A Level or less

##### Other areas of specialty/work

Anesthesiology

##### Street address

Isfahan University Of Medical Sciences., Hezar Jerib St.

##### City

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##### Province

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

### 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

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

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

Not applicable

### Title and more details about the data/document

Only registered symptoms can be published without mentioning the names of the participants

### When the data will become available and for how long

Start of access period 6 months after printing the results up to one year after printing

### To whom data/document is available

Only available to scholars working in academia and academia

### Under which criteria data/document could be used

Written request via email(hossein.naderi1374@gmail.com) and university approval

### From where data/document is obtainable

By contacting the corresponding author

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

After the email is received by the applicant, it takes one week to agree The university will be obtained and then will be notified to the requestor. Maximum of this process takes ten days.

### Comments