

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Prophylactic effects of Ketamine gargle on post-operative sore throat: A double blinded randomized controlled trial

#### Protocol summary

##### Study aim

determining the effect of two different dose of ketamine gargling on the incidence and severity of postoperative sore throat.

##### Design

double blind, randomized controlled trial

##### Settings and conduct

After obtaining written informed consent, 96 patients were assigned to 3 groups equally by computer based block design random allocation. Group K received 50 mg Ketamine solved in 29 ml saline, group G received 100 mg Ketamine solved in 28 ml saline and group C received 30 ml saline as control group. 30 ml of these prepared solutions spilled in the same opaque containers and were given to patients by a nurse to gargle for 30 seconds 5 minutes prior to intubation. This nurse didn't have any more roll during the study. Patients couldn't be unaware about the prepared solutions due to different flavors of them.

##### Participants/Inclusion and exclusion criteria

inclusion criteria: class I and II American Society of Anesthesiologists (ASA) classification system, age range of 18-65 years old, candidates of elective Septo-plasty surgery with general anesthesia, no pre-operative sore throat, no asthma and no sensitivity to using drugs. Exclusion criteria include: try for ET intubation more than one time and change of anesthetic technique.

##### Intervention groups

1- 50 mg Ketamine solved in 29 ml saline. 2- 100 mg Ketamine solved in 28 ml saline

##### Main outcome variables

Post- operative sore throat

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101211005362N22**

Registration date: **2018-09-17, 1397/06/26**

Registration timing: **prospective**

Last update: **2019-02-13, 1397/11/24**

Update count: **1**

##### Registration date

2018-09-17, 1397/06/26

##### 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

2018-09-20, 1397/06/29

##### Expected recruitment end date

2018-11-20, 1397/08/29

##### Actual recruitment start date

2018-09-20, 1397/06/29

##### Actual recruitment end date

2018-11-20, 1397/08/29

##### Trial completion date

2018-11-20, 1397/08/29

##### Scientific title

Prophylactic effects of Ketamine gargle on post-operative sore throat: A double blinded randomized controlled trial

##### Public title

effect of Ketamine gargle on post-operative sore throat

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

patients in class I and II American Society of Anesthesiologists (ASA) classification system, age range of 18-65 years old candidates of elective septoplasty surgery with general anesthesia no pre-operative sore throat no asthma no sensitivity to using drugs.

### Exclusion criteria:

endotracheal tube intubation more than one time change of anesthetic technique.

## Age

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

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

## Sample size

Target sample size: **96**

Actual sample size reached: **96**

## Randomization (investigator's opinion)

Randomized

## Randomization description

computer based block design random allocation

## Blinding (investigator's opinion)

Double blinded

## Blinding description

96 patients were assigned to 3 groups equally by computer based block design random allocation.

## Placebo

Used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethic committee of Isfahan University of Medical Sciences

##### Street address

Hezar.Jerib

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Approval date

2016-05-25, 1395/03/05

##### Ethics committee reference number

ir.mui.rec.1395.3.502

### 2

#### Ethics committee

##### Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

##### Street address

Hezar-Jerib

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Approval date

2016-05-25, 1395/03/05

##### Ethics committee reference number

ir.mui.rec.1395.3.502

## Health conditions studied

### 1

#### Description of health condition studied

Intubation side effect

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

post operative sore throat

#### Timepoint

time 1 was immediately after entrance to recovery room , time 2 was 2 hours post operation , time 3 was 4 hours post operation , time 4 was 8 hours post operation and time 5 was 24 hours after operation.

#### Method of measurement

. Score 0 defined as no sore throat. Score 1 defined as mild sore throat which means sore throat complain only after patients were asked. Score 2 defined as moderate sore throat which means patients complained about sore throat at recovery room before they were asked. Score 3 defined as severe sore throat which means vocal changes or sore throat with hoarseness.

## Secondary outcomes

### 1

#### Description

complications like headache, nausea, vomiting,

dizziness, cough and laryngospasm

### Timepoint

time 1 was immediately after entrance to recovery room , time 2 was 2 hours post operation , time 3 was 4 hours post operation , time 4 was 8 hours post operation and time 5 was 24 hours after operation.

### Method of measurement

asking patients and observation

## Intervention groups

### 1

#### Description

Intervention group: Group K received 50 mg Ketamine solved in 29 ml saline

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: , group G received 100 mg Ketamine solved in 28 ml saline

#### Category

Treatment - Drugs

### 3

#### Description

Control group: group C received 30 ml saline

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kashani hospital

##### Full name of responsible person

dr.Azim Honarmand

##### Street address

Ayatol'a Kashani st,Felezi bridge, Isfahan,Iran

##### City

Isfahan

##### Province

Isfahan

##### Postal code

81746-73461

##### Phone

+98 31 3233 0091

##### Fax

##### Email

Kashani@domain.com

##### Web page address

http://kashani.mui.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Esfahan University of Medical Sciences

##### Full name of responsible person

Dr. Shaghayegh Haghjooy Javanmard

##### Street address

Isfahan University of Medical Sciences

##### City

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##### Province

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##### Postal code

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##### Phone

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##### Fax

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##### Email

sh\_haghjoo@med.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

Mohammadreza Safavi

##### Position

professor

##### Latest degree

Medical doctor

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

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**Position**

professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

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**Name of organization / entity**

Esfahan University of Medical Sciences

**Full name of responsible person**

Mohammadreza Safavi

**Position**

Professor

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

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8145831451

**Phone**

+98 31 3222 2135

**Fax**

+98 31 3222 2135

**Email**

safavi@med.mui.ac.ir

## 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**

Undecided - It is not yet known if there will be 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**

Not applicable

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

collected for the primary outcome measure only

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

date relative to the time when summary data are published

**To whom data/document is available**

no limitation

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

no limitation

**From where data/document is obtainable**

contact to: safavi@med.mui.ac.ir

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

no limitation

**Comments**

no comments