Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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

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Mohammadreza Safavi

Name of organization / entity
Anesthesiology and Critical Care Research Center, Isfahan University of Medical Sciences, Isfahan

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Iran (Islamic Republic of)

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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

Isfehan

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

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Province

Isfehan

Postal code

81746-73461

Approval date

2016-05-25, 1395/03/05

Ethics committee reference number

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Dr. Shaghayegh Haghjooy Javanmard

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Email

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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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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