

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A clinical trial to comparison the effectiveness of Sufentanil and ketamine gargle on postoperative sore throat after laryngeal mask insertion in patients undergoing cataract surgery.

Protocol summary

Summary

Objective: To compare the effectiveness of Sufentanil and ketamine gargle on postoperative sore throat after laryngeal mask insertion in patients undergoing cataract surgery. Design: A not blinded, block randomized clinical trial. Study population: Patients who undergoing cataract surgery following general anesthesia and laryngeal mask insertion. Inclusion criterion: Patients undergoing cataract surgery less than 60 minutes; aged between 18 and 80 years. Exclusion criteria: Surgery for more than 2 hours; taking the NSAIDS in the past 2 days; addiction and smoking; drug allergies; difficult in laryngeal mask insertion; upper respiratory tract infection; asthma; history of sore throat; obesity; neuromuscular disorders; mental disorder; straining during extubation. Sample size: 297 cases. Study intervention: The control group are revising 20 ML of normal saline, intervention group one are revising 50 Mg of ketamine with 20 ML of normal saline and intervention group two are revising 10 Mg of Sufentanil with 20 ML of normal saline and will gargle for 30 minutes before anesthesia. Study outcome: Evaluation and comparison of sore throat based on visual analogue scale (VAS) and sore throat pain intensity based on generalized estimating equation (GEE) at 3, 6, 12, 24 hours after surgery in intervention groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201511014780N8**
Registration date: **2016-05-21, 1395/03/01**
Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-05-21, 1395/03/01

Registrant information

Name

Mohammad Alipour

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2016-07-22, 1395/05/01

Expected recruitment end date

2018-03-22, 1397/01/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A clinical trial to comparison the effectiveness of Sufentanil and ketamine gargle on postoperative sore throat after laryngeal mask insertion in patients undergoing cataract surgery.

Public title

Postoperative sore throat (PST) after use of a laryngeal mask airway

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criterion: Patients undergoing cataract surgery less than 60 minutes; aged between 18 and 80 years.

Exclusion criteria: Surgery for more than 2 hours; taking the NSAIDs in the past 2 days; addiction and smoking; drug allergies; difficult in laryngeal mask insertion; upper respiratory tract infection; asthma; history of sore throat; obesity; neuromuscular disorders; mental disorder; straining during extubation.

Age

From **15 years** old to **80 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **297**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi building, Daneshgah Street

City

Mashhad

Postal code

9138813944

Approval date

2012-09-22, 1391/07/01

Ethics committee reference number

910569

Health conditions studied

1

Description of health condition studied

Sore throat

ICD-10 code

J39.9

ICD-10 code description

Disease of upper respiratory tract, unspecified

Primary outcomes

1

Description

The sore throat

Timepoint

3, 6, 12 and 24 hours after surgery

Method of measurement

visual analogue scale (VAS)

Secondary outcomes

1

Description

Sore throat pain intensity

Timepoint

3, 6, 12 and 24 hours after surgery

Method of measurement

Generalized estimating equation (GEE)

Intervention groups

1

Description

Control group: who are revising 20 ML of normal saline and will gargle for 30 minutes before anesthesia.

Category

Prevention

2

Description

Intervention group 1: who are revising 50 Mg of ketamine with 20 ML of normal saline and will gargle for 30 minutes before anesthesia.

Category

Treatment - Drugs

3

Description

Intervention group 2: who are revising 10 Mg of Sufentanil with 20 ML of normal saline and will gargle for 30 minutes before anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatam-al-Anbia Hospital

Full name of responsible person

Mohammad Alipour

Street address

Khatam-al-Anbia Hospital-Abotaleb Intersection
toward Ferdosi Square

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of
Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Vice Chancellor for Research, Mashhad University of
Medical Sciences, Ghoreishi building, Daneshgah
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City

Mashhad

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for Research, Mashhad University of
Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Alipour

Position

Anesthesiologist- Associate Professor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Masoume Sadeghi

Position

Student in PhD Epidemiology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty