Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effect of Intravenous dexamethasone vs. ketamine gargle vs. intravenous dexamethasone combined with ketamine gargle on post operative sore throat and hoarseness

Protocol summary

Summary

This study was performed to evaluate the efficacy of intravenous dexamethasone plus ketamine gargle for reducing the incidence and severity of post operative sore throat and hoarseness. The main Inclusion criteria were : Patients between 18 and 65 years of age,with American society of anesthesiologists physical status (ASA) I–II, who were scheduled for elective surgery under general anesthesia in Kashni hospital of Isfahan city that requiring one-lung ventilation and the main exclusion criteria was; those who required more than one attempt for tracheal intubation.This double blind clinical trial was performed on140 patients. Patients were randomly allocated into four groups of 35 subjects each: before induction of anesthesia,Group K, gargled 40mg ketamine in 30 ml saline; Group D, were infused 0.2 mg/kg intravenous (IV) dexamethasone; Group KD, gargled 40mg ketamine in 30ml saline plus 0.2mg/kg intravenous dexamethasone; Group P (placebo) that received saline (gargle and IV). Post operative sore throat and hoarseness were graded at 0, 2, 4,8,16 and 24 h after operation on a four-point scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201305165362N5**
Registration date: **2013-06-12, 1392/03/22**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-06-12, 1392/03/22

Registrant information

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Recruitment status

Recruitment complete

Funding source

Isfahan University of Medical Sciences,

Expected recruitment start date

2011-10-01, 1390/07/09

Expected recruitment end date

2012-10-01, 1391/07/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Intravenous dexamethasone vs. ketamine gargle vs. intravenous dexamethasone combined with ketamine gargle on post operative sore throat and hoarseness

Public title

Evaluation of the effect of Intravenous dexamethasone vs. ketamine gargle vs. intravenous dexamethasone combined with ketamine gargle on post operative sore throat and hoarseness

Purpose

Prevention

Inclusion/Exclusion criteria

Patients without a history of preoperative sore throat and asthma;Patients without recent NSAID medication; mouth opening of >3.5cm;a Cormack score of lower than 4; patients with duration of surgery between 60-300 min ;known allergies to study drugs; known difficulty with tracheal intubation. Exclusion criteria were: Those who required more than one attempt for tracheal intubation; Patients with the requirement of mechanical lung ventilation after surgery in the intensive care unit.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

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

Street address

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

City

Isfahan

Postal code

8174675731

Approval date

2011-07-06, 1390/04/15

Ethics committee reference number

390193

Health conditions studied

1

Description of health condition studied

acute sore throat

ICD-10 code

J02.9

ICD-10 code description

Acute pharyngitis, unspecified

2

Description of health condition studied

hoarseness

ICD-10 code

R49.0

ICD-10 code description

Dysphonia

Primary outcomes

1

Description

sore throat

Timepoint

On arrival in the post-anesthesia care unit (0 h), and at 2, 4, 8,16and 24 h thereafter,

Method of measurement

0, no sore throat; 1, mild sore throat (complains of sore throat only on asking); 2, moderate sore throat (complains of sore throat on his/her own); and 3, severe sore throat (change of voice or hoarseness, associated with throat pain).

2

Description

hoarseness

Timepoint

On arrival in the post-anesthesia care unit (0 h), and at 2, 4, 8,16and 24 h thereafter,

Method of measurement

watching-0, No hoarseness; 1, Hoarseness at the time of interview, but noted only by patient; 2, Hoarseness that is readily apparent, but mild; 3, Hoarseness that is readily apparent and severe.

Secondary outcomes

1

Description

Recovery time(min)

Timepoint

times from discontinuation of anesthesia until the time to achieve a modified Aldrete score of 9

Method of measurement

aldrete score

2

Description

the duration of tracheal intubation

Timepoint
the duration of tracheal intubation
Method of measurement
watching

3

Description
Sedation
Timepoint
during interviewed the patients to investigate the POST(post operative sore throat) (0,2,4,8,16,24h after tracheal extubation)
Method of measurement
using the four-point Observer's Assessment of Alertness/ Sedation (OAA/S) scale (where 0 = awake/alert and 3 = deep sleep)

Intervention groups

1

Description
Group K, who gargled 40mg ketamine in 30 ml normal saline for 30 s and received 2mg/kg intravenous saline, 5 min before induction anesthesia.
Category
Prevention

2

Description
Group D, who gargled 30ml normal saline for 30 s and received 0.2mg/kg intravenous dexamethasone, 5min before induction anesthesia.
Category
Prevention

3

Description
Group KD, who gargled 40 mg ketamine in 30 ml normal saline and received 0.2mg/kg intravenous dexamethasone, 5min before induction anesthesia.
Category
Prevention

4

Description
Group P who received a placebo of normal saline (gargled 30 ml normal saline for 30 s and received 0.2mg/kg intravenous normal saline, 5min before induction of anesthesia).
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Kashani hospital
Full name of responsible person
Dr Azim Honarmand
Street address
Isfahan,Kashani street,Kashani hospital,
City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Anesthesiology and Critical Care Research Center,Isfahan University of Medical Sciences, Isfahan, Ir
Full name of responsible person
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Anesthesiology and Critical Care Research Center,Isfahan University of Medical Sciences, Isfahan, Iran
City
Isfarhan
Grant name
ندارد
Grant code / Reference number
no
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Anesthesiology and Critical Care Research Center,Isfahan University of Medical Sciences, Isfahan, Ir
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
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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