

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Effect of lidocaine gargle on sore throat and cough caused by endotracheal intubation in Amir Alam Hospital

Protocol summary

Summary

Sore throat and cough are common complications after general anesthesia. This study has been designed to determine the effect of lidocaine gargle on the sore throat and cough after surgery caused by endotracheal intubation. 54 patients were enrolled in this study. They had between 18 and 80 years old and they candidate for elective ear surgery under general anesthesia with tracheal intubation in Amir Alam Hospital in the spring and summer of 2009. Exclusion criteriaes were difficult intubation, more than twice trying to intubation, operating time less than 60 minute and more than 180 minute and history of taking any medication and abuse of drugs. The patients randomly divided into two groups. First group gargled 1.5 mg/ kg Lidocaine in 30cc normal saline and 30 cc normal saline was gargled by second group five minutes before induction of anesthesia for 30 seconds. Two groups had similar method of anesthesia induction, maintenance and extubation. All information's by questionnaire , gather by a trained person was achieved in the recovery room after full consciousness and 2 hours, 4 hours and 12 hours after surgery. The questionnaires have been considered 0 to 3 score for sore throat and cough severity.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201201028589N1**

Registration date: **2012-02-22, 1390/12/03**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-02-22, 1390/12/03

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2010-03-21, 1389/01/01

Expected recruitment end date

2010-09-23, 1389/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of lidocaine gargle on sore throat and cough caused by endotracheal intubation in Amir Alam Hospital

Public title

Effect of gargle on sore throat and cough caused by general anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: patients candidate for elective ear surgery under general anesthesia with orotracheal intubation ; ASA physical status class I or II;age between 18 and 80 years old. Exclusion criteria: Patients with

operation time less than 60 minute and more than 180 minutes; anticipated difficult intubation; more than twice trying to intubation; NG tube need; upper respiratory tract infection; liver disease; opioid addiction; recent use of pain killers.

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **54**

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

Tehran University of Medical Sciences

Street address

keshavarz bulvard,ghods street

City

tehran

Postal code

Approval date

2010-04-21, 1389/02/01

Ethics committee reference number

89-01-48-10535

Health conditions studied

1

Description of health condition studied

sore throat

ICD-10 code

j02

ICD-10 code description

Acute pharyngitis

Primary outcomes

1

Description

Sore throat

Timepoint

in PACU and 2, 4 and 12 hours after surgery

Method of measurement

Assessment carried out by trained nurses using the questionnaire.0 :No pain .1:mild pain, 2 : moderate pain, 3: sever pain

Secondary outcomes

1

Description

cough

Timepoint

in PACU and 2, 4 and 12 hours after surgery

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group gargled 1.5 mg/ kg Lidocaine in 30cc normal saline five minutes before induction of anesthesia for 30 seconds

Category

Prevention

2

Description

30 cc normal saline was gargled by second group five minutes before induction of anesthesia for 30 seconds

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Amir Alam Hospital

Full name of responsible person

Street address

north sadi

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research

Full name of responsible person

Mrs Norozzade

Street address

Ghods Street, Keshavarz Bulvar

City

Tehran

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

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**

Tehran University of Medical Science

Full name of responsible person

Fatemeh Hajimohamadi

Position

anesthesiologist

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Web page address**Person responsible for updating data****Contact****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*