Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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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 Bulvard
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
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Fatemeh Hajimohamadi
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anesthesiologist
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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