Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Controlled comparison between lidocaine and beclomethasone spray to reduce postoperative sore throat and cough.

Protocol summary

Summary

Sore throat and hoarseness are common complications after endotracheal intubation, with the incidence ranging from 6.6 to 90%. They may be distressing and leave the patient with an unpleasant memory of the operation. Incidence depends on various factors like age, sex, the size of the endotracheal tube, the cuff pressure, the duration for which the tube is in place, the time and manipulations needed to insert the tube, number of suctioning attempts and others. ninthy patients were randomly allocated into3 groups. The ETT cuffs in each group were sprayed with beclomethasone, 10% lidocaine hydrochloride, or normal saline before endotracheal intubation. After insertion, the cuffs were inflated to an airway leak pressure of 25 cm H2O. The patients were examined for sore throat (none, mild, moderate, or severe) each 6 h to 24 hours after extubation. Occurance of cough, laryngospasm were continously monitored and recorded during the observational period.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201012135381N1**
Registration date: **2013-07-28, 1392/05/06**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-07-28, 1392/05/06

Registrant information

Name

Nadia Banihashem

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor of Research Babol University of Medical Sciences

Expected recruitment start date

2009-10-23, 1388/08/01

Expected recruitment end date

2010-10-23, 1389/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Controlled comparison between lidocaine and beclomethasone spray to reduce postoperative sore throat and cough.

Public title

Controlled comparison between lidocaine and beclomethasone spray to reduce postoperative sore throat and cough

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: ASA physical status I to II; aged 18 to50years; surgical procedures under general anesthesia with orotracheal intubation in the supine position; not using corticosteroids and analgesics before operation. exclusion criteria: patients undergoing oral cavity surgery; cervical spine surgery; thyroid surgery;patients

with a difficult airway (after >1 orotracheal intubation attempt); smoker; history of bronchial asthma; requiring a nasogastric tube;or a history of perioperative sore throat.

Age
From **18 years** old to **50 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **90**

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
Babol University of Medical Sciences

Street address
Daneshgah Sq - Ganjafrooz Ave

City
Babol

Postal code

Approval date
2009-06-27, 1388/04/06

Ethics committee reference number
3724/30/پ/ژ

Health conditions studied

1

Description of health condition studied
Complication of intubation

ICD-10 code
Y70

ICD-10 code description
Anaesthesiology devices associated with adverse incidents

Primary outcomes

1

Description
sore throat

Timepoint
1 and 24 hour after extubation

Method of measurement
history taking

2

Description
cough

Timepoint
1 and 24 hour after extubation

Method of measurement
history taking

3

Description
hoarseness

Timepoint
1 and 24 hour after extubation

Method of measurement
history taking

Secondary outcomes

1

Description
blood pressure

Timepoint
Before intubation, 1,3,5 minutes after intubation, before extubation, 1,3,5 minutes after intubation

Method of measurement
Noninvasive cuff measurrment

2

Description
heart rate

Timepoint
Before intubation, 1,3,5 min after intubation,, before extubation, 1,3,5minutes after intuba minutes after intubation

Method of measurement
Pulse counting

Intervention groups

1

Description
Intervention: Before endotracheal intubation, 10% lidocaine was sprayed on the distal end of the endothracheal tube

Category
Prevention

2

Description
Intervention: Before endotracheal intubation, beclomethasone was sprayed on the distal end of the endothracheal tube
Category
Prevention

3

Description
Control: Before endotracheal intubation, normal saline 5% was sprayed on the distal end of the endothracheal tube
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Ayatollah Ruhani Hospital
Full name of responsible person
Dr Nadia Banihashem
Street address
City
babol

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice-chancellor of Research Babol University Of Medical Sciences
Full name of responsible person
Dr Amrolah Mostafazadeh
Street address
Daneshgah Square, Ganjafrooz Avenue, Vice-chancellor Of Research
City
Babol
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-chancellor of Research Babol 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
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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