

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 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. ninety patients were randomly allocated into 3 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. Occurrence of cough, laryngospasm were continuously 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

Babol University Of Medical Sciences

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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 to 50 years; 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

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 measurment

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 endotracheal tube

Category

Prevention

2

Description

Intervention: Before endotracheal intubation, beclomethasone was sprayed on the distal end of the endotracheal tube

Category

Prevention

3

Description

Control: Before endotracheal intubation, normal saline 5% was sprayed on the distal end of the endotracheal 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

Babol University of Medical Sciences

Full name of responsible person

Dr Nadia Banihashem

Position

Assistant Professor of Anesthesiology

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