

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effects of intracuff dexamethasone, intravenous dexamethasone & application of bethametasone ointment on endotracheal tube cuff on Post-intubation sore throat

Protocol summary

Summary

Sorethroat is a common problem after general anesthesia. It may be seen after using tracheal tube, laryngeal mask air way or even anesthesia face mask. In this study the efficacy of intracuff dexamethasone, intravenous dexamethasone & lubricating cuff & distal end of tracheal tube with betametasone ointment on sorethroat are compared. A total of 120 patients, American Society of Anesthesiologists (ASA) class 1 – 2, scheduled for elective abdominal or orthopedic operations under general anesthesia are enrolled in this double blind clinical trial study. All the patients are randomly allocated to four groups: the endotracheal tube cuffs of the patients in the first group are filled with 16 mg dexamethasone. Patients in the second group receive 8 mg dexamethasone intravenously. In the third group cuff and distal end of the endotracheal tubes are lubricated with betametasone ointment and in the fourth group cuffs are filled with air as usual. Frequency of sore throat and its intensity on a visual analog scale (VAS) are assessed in each group after recovery period and 8 and 24 hours after that. The data are transferred to SPSS 18 software and analyzed statically with chi-square and ANOVA tests. P value less than 0.05 is considered significant.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201302178531N2**
Registration date: **2013-03-07, 1391/12/17**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-03-07, 1391/12/17

Registrant information

Name

Ladan Ansari

Name of organization / entity

Islamic Azad University, Tehran Medical Branch

Country

Iran (Islamic Republic of)

Phone

+98 21 8876 4030

Email address

lansari@iautmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Islamic Azad University - Tehran Medical Branch

Expected recruitment start date

2009-08-06, 1388/05/15

Expected recruitment end date

2010-08-06, 1389/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of intracuff dexamethasone, intravenous dexamethasone & application of bethametasone ointment on endotracheal tube cuff on Post-intubation sore throat

Public title

Effects of intracuff dexamethasone, intravenous dexamethasone & application of bethametasone ointment on endotracheal tube cuff on Post-intubation

sore throat

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria: 60>age>18 yr; ASA class 1 or 2; no URI infection or sorethroat at the time of surgery; no possibility of difficult air way; no candidate of surgery on air way; candidate of general anesthesia & tracheal intubation; no contraindication for receiving steroids.
Exclusion criteria: intraoperation pharyngeal packing; intraoperation NG tube placement.

Age
From **18 years** old to **60 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tehran Medical Branch of Islamic Azad University

Street address

Islamic Azad University - Tehran Medical Branch, Khaghani st.

City

Tehran

Postal code

Approval date

2009-08-05, 1388/05/14

Ethics committee reference number

13610101861085

Health conditions studied

1

Description of health condition studied

prevention of sore throat after tracheal intubation

ICD-10 code

Y70

ICD-10 code description

Anaesthesiology devices associated with adverse incidents

Primary outcomes

1

Description

sore throat after tracheal intubation

Timepoint

After recovery period, 8 & 24 hours after intervention

Method of measurement

Questionnaire & VAS method

Secondary outcomes

empty

Intervention groups

1

Description

First group: Intracuff application of 16 mg dexamethasone.

Category

Prevention

2

Description

Third group: application of bethametasone ointment on endotracheal tube cuff.

Category

Prevention

3

Description

Second group: Intravenous application of 8 mg dexamethasone.

Category

Prevention

4

Description

Fourth group or control group: filling the endotracheal tube cuff with air.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Booali hospital
Full name of responsible person
Ladan Ansari
Street address
Damavand st.
City
Tehran

empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Ladan Ansari
Full name of responsible person
Ladan Ansari
Street address
N.1 - 26 Alley, Dr. Ghandi st., North Sohrevardi st.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ladan Ansari
Proportion provided by this source
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

2

Sponsor

Name of organization / entity
Islamic Azad University, Tehran Medical Branch, Vice
chancellor for research
Full name of responsible person
Dr. Seyedshahabedin Mohseni
Street address
Islamic Azad University, Tehran Medical Branch,
Zargande, Shariati ST.
City
Tehran
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Islamic Azad University, Tehran Medical Branch, Vice
chancellor for research
Proportion provided by this source
Public or private sector

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran Medical Branch of Islamic Azad University
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Ladan Ansari
Position
Professor assistant of anesthesiology
Other areas of specialty/work
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Person responsible for scientific inquiries

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Ladan ansari
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Person responsible for updating data

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Web page address

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