

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparative evaluation of intracuff ropivacaine, bupivacaine, and lidocaine on emergence reactions after general anesthesia

Protocol summary

Study aim

This study was designed to investigate the effect of intracuff local anesthetics on emerging reactions after general anesthesia.

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 350 patients. Random card selection method is used for randomization.

Settings and conduct

In the operating room of Imam Hossein (AS) Hospital in Tehran, before performing anesthesia, an anesthesia technician, without informing the anesthesiologist and the patient, uses a random selection of a card to identify the patient group and one of the syringes containing one of the drugs in each group. Submits to the anesthesiologist and records this information separately. At the end of the surgery, the questionnaire is delivered to the first technician. Information outside the operating room is tracked by the same anesthesiologist.

Participants/Inclusion and exclusion criteria

All patients over 18 years of age with physical condition I or II of the American Society of Anesthesiologists (ASA) who undergo elective limb surgery under general anesthesia for one to three hours by endotracheal intubation in a supine position are included in the study. To be. Patients with a history of sore throat, hoarseness or cough, moderate to severe illness, recent respiratory infection, history of airway prolapse, long history of intubation, smokers and illicit drug users, difficult to predict intubation, risk of aspiration Stomach contents, history of tracheal or laryngeal surgery, BMI> 30.0, use of a nasogastric tube or nasal or oral airway will be excluded.

Intervention groups

After endotracheal intubation, the endotracheal tube cuff will be filled in one of the following ways: air, isotonic saline, ropivacaine, bupivacaine, lidocaine.

Main outcome variables

Cough; Sore throat; bucking on the endotracheal tube

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120910010800N4**

Registration date: **2022-04-23, 1401/02/03**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-23, 1401/02/03**

Update count: **0**

Registration date

2022-04-23, 1401/02/03

Registrant information

Name

Dariusht Abtahi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 21 2263 2611

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-20, 1401/01/31

Expected recruitment end date

2022-07-22, 1401/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparative evaluation of intracuff ropivacaine, bupivacaine, and lidocaine on emergence reactions after general anesthesia

Public title
Evaluation of the effect of using local anesthetics inside the endotracheal tube cuff on emergence reactions from anesthesia

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age older than 18 years old
 Consent to the study
 Performing general anesthesia using endotracheal intubation
Exclusion criteria:
 Drug abuse
 Existence of uncontrolled underlying disease
 Pre-existing sore throat
 Pre-existing hoarseness
 Pre-existing cough
 Recent respiratory infection
 History of hyperactive airways
 History of prolonged intubation
 Anticipated difficult intubation
 Risk of aspiration of gastric contents

Age
From **18 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size
Target sample size: **350**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients are grouped by a simple randomization method using a random selection of one of the five cards, each of which is named after one of the groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
Before performing anesthesia, an anesthesia technician, without the knowledge of the anesthesiologist and the patient, uses a random selection of a card to identify the patient group and deliver one of the syringes containing one of the drugs in each group to the anesthesiologist and record this information separately. At the end of the surgery, the questionnaire is delivered to the first technician. Information outside the operating room is tracked by the same anesthesiologist.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Vice-Chancellor in Research Affairs - Shahid Beheshti University

Street address

Emam Hossein Hospital, Shahid Madani St.

City

Tehran

Province

Tehran

Postal code

1617763141

Approval date

2019-05-05, 1398/02/15

Ethics committee reference number

IR.SBMU.RETECH.REC.1398.032

Health conditions studied

1

Description of health condition studied

Cough, sore throat, and hoarseness after extubation

ICD-10 code

T88.9XXA

ICD-10 code description

Complication of surgical and medical care, unspecified, initial encounter

Primary outcomes

1

Description

Cough

Timepoint

At zero, ten minutes, thirty minutes, 6 hours, and 24 hours after extubation

Method of measurement

Anesthesiologist observation to determine its presence and severity (mild: less than 5 coughs, moderate: more than 5 coughs, severe: frequent coughs that prevent the patient from breathing normally)

2

Description

Sore throat

Timepoint

At zero, ten minutes, thirty minutes, 6 hours, and 24 hours after extubation

Method of measurement

Patient self-reported based on either three, moderate, or severe levels.

3

Description

Hoarseness

Timepoint

At zero, ten minutes, thirty minutes, 6 hours, and 24 hours after extubation

Method of measurement

Observe an anesthesiologist by determining its presence and severity (mild: ability to speak easily with slight change in voice, moderate: difficulty speaking, severe: complete hoarseness)

Secondary outcomes

empty

Intervention groups

1

Description

Control group: In the air group, the endotracheal tube's cuff will be filled with a minimum volume of air so that no sound of air leakage can be heard.

Category

Placebo

2

Description

Intervention group: In the isotonic saline solution group, the cuff of the endotracheal tube will be filled with a minimum volume of isotonic saline solution so that no air leakage sound can be heard.

Category

Treatment - Drugs

3

Description

Intervention group: In the ropivacaine group, the endotracheal tube's cuff will be filled with a minimum volume of 0.5% ropivacaine so that no air leakage can be heard.

Category

Treatment - Drugs

4

Description

Intervention group: In the bupivacaine group, the endotracheal tube's cuff will be filled with a minimum volume of 0.5% bupivacaine so that no air leakage can be heard.

Category

Treatment - Drugs

5

Description

Intervention group: In the lidocaine group, the endotracheal tube's cuff will be filled with a minimum

volume of 2% lidocaine so that no air leakage can be heard.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hospital Emam Hossein

Full name of responsible person

Dariusht Abtahi

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<https://www.ehmc.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Afshin Zarghi

Street address

Velenjak, 7th Floor, Bldg No.2 SBUMS, Arabi Ave

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Intl_office@sbmu.ac.ir

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahid Beheshti University of Medical Sciences

Proportion provided by this source

100

Public or private sector

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

Person responsible for general inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Dariush Abtahi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All data is potentially shareable after unidentified individuals.

When the data will become available and for how long

One year after the publication of the article.

To whom data/document is available

All jobs

Under which criteria data/document could be used

All non-personal patient information (anonymously) can be accessed by contacting the responsible author.

From where data/document is obtainable

email to: drdariushabtahi@yahoo.com

What processes are involved for a request to access data/document

Sending email and review by the responsible author

Comments