

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation and Comparison of Intracuff Alkalinized Lidocaine versus Intravenous Lidocaine effects on Coughing and Postoperative Sore throat

Protocol summary

Study aim

Determination and Comparison of the effect of Intracuff Alkalinized Lidocaine versus IV Lidocaine on Coughing and Postoperative Sore Throat

Design

Randomized controlled double blinded clinical trial on 99 patients undergoing intubation. Patients were randomly divided into three groups with Simple randomization by Random Allocation Software.

Settings and conduct

A randomized clinical. The population of study were 99 patients from Kashani hospital. The study was conducted between 2017 and 2018. The method of blinding was used to prevent patients from being aware of the substance used during intubation, samples were collected by an anesthetist unaware of the type of used anesthetic agents and also administration of drugs was done by another anesthetist.

Participants/Inclusion and exclusion criteria

Patients with ASA I or ASA II Patients aged 18 to 65 years
Patients who were candidates for Elective Surgery under General Anesthesia requiring Tracheal Intubation were enrolled in the study. Patients with Underlying Conditions including Uncontrolled Diabetes, Uncontrolled Hypertension, Asthma Patients with Hyper-Reactive Airway Disease Patients with history of Lidocaine Susceptibility Patients with Chronic Cough and Sore Throat were considered as exclusion criteria.

Intervention groups

Intracuff alkalinized lidocaine group: The cuff of endotracheal tube was slowly filled with air then 2 ml of lidocaine was injected into the cuff. Finally, an additional volume of NaHCO₃ 8.4% was injected into the cuff.
intravenous lidocaine group: The cuff of endotracheal tube was filled with air, at the end of the surgery and after extubation 1.5 mg/kg lidocaine was injected intravenously. Control group: The cuff of endotracheal tube was filled only with air to the pressure of 30 cmH₂O.

Main outcome variables

Changing in frequency of cough after intubation;
Changing in severity of sore throat after intubation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20090129001615N3**

Registration date: **2019-11-04, 1398/08/13**

Registration timing: **retrospective**

Last update: **2019-11-04, 1398/08/13**

Update count: **0**

Registration date

2019-11-04, 1398/08/13

Registrant information

Name

Azim Honarmand

Name of organization / entity

Alzahra hospital

Country

Iran (Islamic Republic of)

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+98 31 3668 0048

Email address

honarmand@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-01, 1396/07/09

Expected recruitment end date

2018-10-01, 1397/07/09

Actual recruitment start date

2017-10-01, 1396/07/09

Actual recruitment end date

2018-10-01, 1397/07/09

Trial completion date

2018-10-01, 1397/07/09

Scientific title

Evaluation and Comparison of Intracuff Alkalinized Lidocaine versus Intravenous Lidocaine effects on Coughing and Postoperative Sore throat

Public title

Evaluation and Comparison of the effect of Intracuff Alkalinized Lidocaine versus Intravenous Lidocaine on Coughing and Sore throat after Surgical Operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with ASA I or ASA II Patients aged 18 to 65 years
Patients who were candidates for Elective Surgery under General Anesthesia requiring Tracheal Intubation

Exclusion criteria:

Patients with Underlying Conditions including Uncontrolled Diabetes, Uncontrolled Hypertension, Asthma Patients with Hyper-Reactive Airway Disease
Patients with history of Lidocaine Susceptibility Patients with Chronic Cough and Sore Throat

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **99**

Actual sample size reached: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with Random Allocation Software

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient is not aware of the Substance used during Intubation. Samples were collected by an Anesthetist unaware of the type of used Anesthetic Agents. (Administration of drugs was done by another Anesthetist.)

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Hezarjerid Ave.

City

Isfahan

Province

Isfahan

Postal code

7346181746

Approval date

2016-06-16, 1395/03/27

Ethics committee reference number

ir.mui.rec.1395.3.972

Health conditions studied

1

Description of health condition studied

Coughing after intubation

ICD-10 code

R05

ICD-10 code description

Cough

2

Description of health condition studied

Sore throat after intubation

ICD-10 code

R07.0

ICD-10 code description

Pain in throat

Primary outcomes

1

Description

postoperative Cough frequency

Timepoint

immediately after extubation, within fifteen minutes, one, two, three, twelve and twenty-four hours after extubation.

Method of measurement

Counting Cough Frequency

2

Description

Postoperative Sorethroat

Timepoint

immediately after extubation, within fifteen minutes, one, two, three, twelve and twenty-four hours after extubation.

Method of measurement

Visual Analogue Scale

kashani@mui.ac.ir

Web page address<https://kashani.mui.ac.ir/>**Secondary outcomes**

empty

Intervention groups**1****Description**

Intervention group: Intracuff Lidocaine Group, The population of the first group was 33. Initially, in this group, the cuff of endotracheal tube was slowly filled with air until no sound of air leakage was heard and then 2 ml of lidocaine was injected into the cuff. Finally, an additional volume of NaHCO₃ 8.4% was injected into the cuff to reach the pressure of 30 cmH₂o inside.

Category

Treatment - Drugs

2**Description**

Intervention group: Intravenous Lidocaine, the cuff of endotracheal tube was filled with air to the pressure of 30 cmH₂o with air; then at the end of the surgery and after extubation 1.5 mg/kg lidocaine was injected intravenously.

Category

Treatment - Drugs

3**Description**

Control group: the cuff of endotracheal tube was filled only with air to the pressure of 30 cmH₂o.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Kashani Hospital

Full name of responsible person

Nazanin Vahedi Nouri

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Kashani Street, Isfahan, Isfahan Province

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8183983333

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Fax**Email****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Web page address<http://med.mui.ac.ir/>**Grant name**

Isfahan University of Medical Sciences, Grant

Grant code / Reference number

395972

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

Yes

Title of funding source

Esfahan 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**

Esfahan University of Medical Sciences

Full name of responsible person

Azim Honarmand

Position

Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

No - There is not 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

Main outcome information

When the data will become available and for how long

Since Publication

To whom data/document is available

Researchers working in academic, scientific and
industrial institutes

Under which criteria data/document could be used

Statistical analysis

From where data/document is obtainable

honarmand@med.mui.ac.ir Dr.Azim Honarmand

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

Send email and mention why you need documentation.

One to two weeks after sending the request

Comments