

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The effect of intravenous lidocaine on reducing the complications of endotracheal intubation after cardiac surgery

Protocol summary

Study aim

The effect of intravenous lidocaine on reducing the complications of endotracheal extubation after heart surgery

Design

A clinical trial with a control group of 45 patients in each group, double-blind, is performed using permuted balanced block (block of four) randomization software. In order to observe concealment and blinding at the same time, the random sequence will be converted into composite codes (not group names) and these codes will be provided to the main researcher in closed envelopes. There is no difference between the two groups of drugs and placebo in terms of appearance, volume and type of syringe.

Settings and conduct

In both groups, patients are selected who have weaning and extubation conditions for at least 6 to 12 hours after surgery. 1.5 ml/kg 10% iv lidocaine is injected intravenously. In the control group, 1.5 cc/kg of normal intravenous saline will be injected at the same time with the same conditions. The syringes containing lidocaine or normal saline are very similar and are coded by a third party to the nursing shift at random based on the number of patients who submit the study conditions and then determined by them to the patients on time.

Participants/Inclusion and exclusion criteria

In both groups, patients are selected who have weaning and extubation conditions for at least 4 to 12 hours after surgery. The patient should have relatively simple heart surgery involving CABG or only single valve surgery

Intervention groups

In a group, 1.5 ml / weight of 2% intravenous lidocaine is injected intravenously (1.5 cc / weight of syringe containing lidocaine at a dose of 1.5) 10 minutes before the endotracheal tube is removed. In the control group, 1.5 cc/kg of normal serum intravenous saline in terms of weight will be injected at the same time with the same conditions

Main outcome variables

Cough, bronchospasm, changes in BP and HR, side effects of lidocaine injection

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211206053291N1**

Registration date: **2022-02-20, 1400/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2022-02-20, 1400/12/01**

Update count: **0**

Registration date

2022-02-20, 1400/12/01

Registrant information

Name

Abdolreza Dayani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2266 3250

Email address

dr.a.dayani@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-08, 1400/10/18

Expected recruitment end date

2022-05-22, 1401/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The effect of intravenous lidocaine on reducing the complications of endotracheal intubation after cardiac surgery

Public title
lidocaine effect on extubation

Purpose
Supportive

Inclusion/Exclusion criteria
Inclusion criteria:
 simple cardiac surgery(CABG or valvular) No history of smoking and drug or alcohol addiction during the last 10 years before surgery No history of any drug or food allergies All patients took beta-blockers around the operation and in the morning No history of lung problems (asthma, COPD, etc.) treated with oral or inhaled drugs
Exclusion criteria:
 Dangerous arrhythmia during or after surgery Hemodynamic instability including: cardiac instability (patients treated with epinephrine or levofed at doses above 1.1 µg / kg) and respiratory instability ($po_2 \leq 60$ mmhg or $pco_2 \geq 50$) during postoperative time Bleeding so much that the patient becomes a candidate for reoperation Injection of lidocaine for any reason after surgery EF drop after surgery Use of ECMO or pump balloons after surgery

Age
From **18 years** old to **85 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization is performed using permuted balanced block (block of four) method. In order to observe concealment and blinding at the same time, the random sequence will be converted into composite codes (not group names) and these codes will be provided to the main researcher in closed envelopes. There is no difference in appearance, volume and type of syringe between the two groups of drugs and placebo During the study, after opening each envelope, a syringe corresponding to that code is given to the patient.

Blinding (investigator's opinion)
Double blinded

Blinding description
Extubating the pt when the patient is calm and breathing

slowly with a spontaneous ventilator mode 1.5 mg / weight of 2% intravenous lidocaine is injected intravenously (1.5 cc / weight of syringe containing lidocaine at a dose of 1.5 ml / cc).In the control group, 1.5 cc of normal serum will be injected intravenously in terms of weight at the same time under the same conditions.Syringes containing lidocaine or normal saline will be exactly the same and will be coded by a third party And delivered to the head of the nursing shift randomly based on the number of patients who have the conditions of study and then injected by them to the patient at a specified time.Heart rate, blood pressure and possible arrhythmia are assessed before and during the injection, 5 minutes after the injection, and finally one minute after the endotracheal tube is removed and 10 minutes after it, and are completed in a special form by the patient's responsible nurse.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of Rajaie Cardiovascular Medical and Research Center

Street address

valiasr st,niyayesh highway,shahid rajaei cardiovascular center

City

tehran

Province

Tehran

Postal code

1995614331

Approval date

2021-12-04, 1400/09/13

Ethics committee reference number

IR.RHC.REC.1400.075

Health conditions studied

1

Description of health condition studied

Larangospasm.

ICD-10 code

J95.5

ICD-10 code description

Postprocedural subglottic stenosis

Primary outcomes

1

Description

Cough occurs after extubation

Timepoint

The onset of cough is assessed before and during injection, 5 minutes after injection, and finally one minute after endotracheal tube removal and 10 minutes after

Method of measurement

The incidence of cough is measured by three criteria of cough, which include: 1- no cough or temporary cough following the exit of the endotracheal tube, 2- incidence of cough by breathing, and 3- persistent cough without respiratory stimulation when the endotracheal tube exits up to 10 minutes later. The questionnaire is mentioned

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 45 patients who have weaning and extubation conditions for at least 6 to 12 hours after surgery. For this purpose, the patient should have relatively simple heart surgery involving vascular occlusion (CABG) or only single valve surgery. Also dangerous arrhythmia and instability. Cardiac (patients treated with epinephrine or Levofed at doses above 1.1 / macro / kg) and respiratory ($po_2 \leq 60$ mmHg or ($pco_2 \geq 50$) are also excluded from our study Our study enters

Category

Treatment - Drugs

2

Description

Control group: For 45 patients, 1.5 cc/kg of normal intravenous saline will be injected at the same time under the same conditions. Syringes containing lidocaine or normal saline will be exactly the same and will be coded by a third person to the nursing shift randomly based on the number of patients The study is delivered and then injected by the patient at a specific time

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shaheed Rajaie Cardiovascular, Medical & Research Center

Full name of responsible person

Abdolreza Dayani

Street address

Valiasr st, niyayesh highway, shahid rajaei cardiovascular center

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Sciences, Tehran, Iran

Full name of responsible person

majid maleki

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Valiasr st, niyayesh highway, Rajaie Cardiovascular Medical and Research Center

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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

Rajaie Cardiovascular Medical and Research Center, Iran University of Medical Sciences, Tehran, Iran

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

Iran University of Medical Sciences

Full name of responsible person

Abdolreza Dayani

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available