Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

The Effect of Carina Anesthesia with Topical Lidocaine in Endotracheal Suction on Hemodynamic parameters and bucking in Adult Patient After Cardiac Surgery

Protocol summary

Study aim
Determining the effect of Karina anesthesia by topical administration of lidocaine on endotracheal suctioning on hemodynamic parameters and strain in adult patients after heart surgery

Design
Clinical trial with control group, double-blind, randomized, phase 2 and 3 on 64 patients. Random number table was used for randomization.

Settings and conduct
The place is Shahid Rajaei Heart Hospital. endotracheal suctioning is performed after the intervention. Changes in hemodynamic and bucking indices are checked 2 minutes before and during and 2 minutes after endotracheal suctioning. The patient and the recorder are kept blind.

Participants/Inclusion and exclusion criteria
entrance: 1. Being in the age range of 18 to 65 years 2. Patients undergoing heart surgery who have undergone one of the following surgeries: coronary, valve, or both. 3- Having a full level of consciousness (15/15) before admission for surgery. 4- Having stability in the hemodynamic range No entry: 1- No airway abnormalities or unusual use of endotracheal tubes 2. No history of lidocaine allergy

Intervention groups
4 cc of 2% lidocaine in the target group and 4 cc of normal saline 0.9% in the control group is apply into the trachea and then the trachea is sucked.

Main outcome variables
Hemodynamic indicators; Cough reflex (bucking)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20201011048991N1**
Registration date: **2020-12-19, 1399/09/29**
Registration timing: **registered_while_recruiting**

Last update: **2020-12-19, 1399/09/29**
Update count: **0**

Registration date
2020-12-19, 1399/09/29

Registrant information

Name
Hoda Abedi

Name of organization / entity
Shahid Rajaei Cardiovascular Research and Therapeutic Training Center

Country
Iran (Islamic Republic of)

Phone
+98 21 2392 3312

Email address
abedi.hoda.ha@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-11-10, 1399/08/20

Expected recruitment end date
2020-12-20, 1399/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The Effect of Carina Anesthesia with Topical Lidocaine in

Endotracheal Suction on Hemodynamic parameters and bucking in Adult Patient After Cardiac Surgery

Public title
"The effect of local anesthesia of carina in suction on hemodynamic and physiological parameters"
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
consent to participate in the study Having a full level of consciousness (15/15) before admission for surgery Having stability in the patient's hemodynamic range Patients who need suction due to accumulation of secretions
Exclusion criteria:
No history of lidocaine allergy Absence of any airway abnormalities or the use of unusual airway endotracheal tubes
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **64**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, random allocation is done in block form. Groups are divided into 8 groups of 8. The target group is named with the letter A and the control group with the letter B. Randomization was performed individually with statistical software. In each block, 4 positions are assigned to A and 4 positions to B. Each of these letters was assigned to a project participant in the order recorded in the block table. Depending on whether it was A or B, lidocaine or normal saline was used during suctioning and the data were recorded.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, the study participant (patient) and the data recorder were kept blind. The procedure is that one nurse is aware of which group the patient is in, and the second nurse writes down the data without knowing the patient group.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shahid Rajaei Cardiovascular Research and Training Center
Street address
Rajaei Heart Center,Valiasr St
City
Tehran
Province
Tehran
Postal code
19969 11151
Approval date
2020-11-07, 1399/08/17
Ethics committee reference number
IR.RHC.REC.1399.089

Health conditions studied

1

Description of health condition studied
tracheal suction
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Hemodynamic parameters
Timepoint
2 minutes before and during and 2 minutes after tracheal suction
Method of measurement
Cardiopulmonary monitoring devices

2

Description
bucking in Intubated patient
Timepoint
2 minutes before and during and 2 minutes after tracheal suction
Method of measurement
Mild (less than 3 times), moderate (between 3 and 5 times), severe (more than 5 times)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 4 cc of 2% lidocaine are apply directly into the carina just before suctioning the trachea.

Category

Prevention

2

Description

Control group: 4 cc of 0.9% Normal saline are apply directly into the carina just before suctioning the trachea.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei cardiovascular center

Full name of responsible person

Hoda Abedi

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Rajaei Heart Center,Valiasr St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Fateme Shima Hadipoorzade

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shimahadipoorzadeh@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rajaei Heart Center

Proportion provided by this source

20

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

2

Sponsor

Name of organization / entity

Rajaei Heart Center

Full name of responsible person

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Grant name

Grant code / Reference number

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

No

Title of funding source

Hoda Abedi

Proportion provided by this source

80

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Rajaei Heart Center

Full name of responsible person

Hoda Abedi

Position

Master student of intensive care nursing

Latest degree
Bachelor
Other areas of specialty/work
Nursery
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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
Yes - There is a plan to make this available
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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Shared through email
When the data will become available and for how long
Access period starts 1year after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
unlimited
From where data/document is obtainable
through email abedi.hoda.ha@gmail.com
What processes are involved for a request to access data/document
1 month after sending the email
Comments
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