

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Assessing of the lidocaine oropharyngeal spray before tracheal intubation on heart rate, blood pressure and arrhythmia in patients undergoing coronary artery bypass graft.

Protocol summary

Study aim

The effect of uropharyngeal lidocaine spray before endotracheal intubation on heart rate, blood pressure and arrhythmia in patients undergoing coronary artery bypass graft surgery

Design

Interventional study with control group, randomized, therapeutic, with parallel groups, 60 patients, In this study, data gathering and analysis will done by another researcher.

Settings and conduct

Seyed Al-Shohada Hospital Patients undergoing CABG were divided into two groups: LS lidocaine spray and control group C, and in LS group, two puffs of lidocaine spray were used 10% before induction of anesthesia and two puffs during laryngoscopy for endotracheal intubation. In the LS group, lidocaine was sprayed into the space of the end of the tongue and around the glottis. And received Vallecula. Maintenance of anesthesia in all patients using isoflurane in oxygen and during cardiopulmonary bypass was by Propofol infusion. If vasoactive drugs were used, the patient was excluded from the study

Participants/Inclusion and exclusion criteria

Inclusion: Patients with cardiac ischemia undergoing CABG
Absence: Patients with a history of previous arrhythmias (Atrial Fibrillation) AF, cardiomyopathy of any cause, renal and hepatic impairment, patients with lidocaine hypersensitivity and patients with airway obstruction or endotracheal intubation for any reason.
Repeated efforts are required

Intervention groups

Patients were divided into two groups: LS lidocaine spray and control group C, and in LS group, two puffs of lidocaine spray were used 10% before induction of anesthesia and two puffs during laryngoscopy for endotracheal intubation.

Main outcome variables

arterial blood pressure, heart rate, arrhythmia,

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170411033365N3**

Registration date: **2022-03-15, 1400/12/24**

Registration timing: **prospective**

Last update: **2022-03-15, 1400/12/24**

Update count: **0**

Registration date

2022-03-15, 1400/12/24

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-04, 1401/01/15

Expected recruitment end date

2022-07-06, 1401/04/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessing of the lidocaine oropharyngeal spray before tracheal intubation on heart rate, blood pressure and arrhythmia in patients undergoing coronary artery bypass graft.

Public title

Assessing of the lidocaine oropharyngeal spray before tracheal intubation on heart rate, blood pressure and arrhythmia in patients undergoing coronary artery bypass graft.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients due to cardiac ischemia undergoing CABG

Exclusion criteria:

Patients with a history of previous arrhythmias (Atrial Fibrillation) AF Have cardiomyopathy of any cause renal and hepatic impairment, patients with lidocaine hypersensitivity patients requiring repeated efforts due to airway obstruction or endotracheal intubation for any reason

Age

No age limit

Gender

Both

Phase

1-2

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: 30

Randomization (investigator's opinion)

Randomized

Randomization description

The patients were randomly divided into two groups via a certified true randomizer number generator (www.random.org, Android Play Store). Two groups of LS lidocaine spray and control group C using random numbers by computer random allocation software, and in the LS group two puffs of lidocaine spray 10% before induction of anesthesia and two puffs during laryngoscopy for the tube

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, data gathering and analysis will done by another researcher.

Placebo

Used

Assignment

Parallel

Other design features

The effect of uropharyngeal lidocaine spray before endotracheal intubation on heart rate, blood pressure

and arrhythmia in patients undergoing coronary artery bypass graft surgery

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Urmia University of Medical Sciences

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Approval date

2021-12-14, 1400/09/23

Ethics committee reference number

IR.UMSU.HIMAM.REC.1400.004

Health conditions studied**1****Description of health condition studied**

Patients with cardiac ischemia undergoing CABG

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

heart rate

Timepoint

baseline (T0), one minute before intervention (T1), 30 seconds (T2) and one minute (T3), two (T4), three (T5)), Four (T6), five (T7), and 10 (T8) after intervention.

Method of measurement

Saadat Cardiac and hemodynamic Monitoring for rate monitoring.

2**Description**

Blood Pressure

Timepoint

baseline (T0), one minute before intervention (T1), 30 seconds (T2) and one minute (T3), two (T4), three (T5)), Four (T6), five (T7), and 10 (T8) after intervention.

Method of measurement

Saadat Cardiac and hemodynamic Monitoring for direct blood pressure monitoring.

3

Description

arrhythmia

Timepoint

baseline (T0), one minute before intervention (T1), 30 seconds (T2) and one minute (T3), two (T4), three (T5) , Four (T6), five (T7), and 10 (T8) after intervention.

Method of measurement

Saadat Cardiac and hemodynamic Monitoring for arrhythmia detection.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In the LS group, two puffs of lidocaine 10% spray were used before induction of anesthesia and two puffs were used before laryngoscopy for endotracheal intubation. Spray solution 100 ml, contains 1000 puffs, each puff contains 10 mg.

Category

Treatment - Drugs

2

Description

Control group: No intervention will be performed in the control group.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Seyed Al-Shohada Hospital

Full name of responsible person

dr.alireza Mahouri

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Alireza Mahoori

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Cardiac Anesthesia

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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