Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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.]n 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 Fibrilation) 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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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 Fibrilation) 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
Street address
Imam Khomeini University Hospital-Ershad AVE-Modarres Blvd- Urmia-IRAN
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Province
West Azarbaijan
Postal code
5715789397
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
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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?
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
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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