

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

Comparison the effect of transtracheal lidocaine and intravenous lidocaine on hemodynamic of Patients with hypertension undergoing drug treatment to tracheal intubation

Protocol summary

Study aim

The aim of this study was to compare the effects of intravenous lidocaine and transtracheal on hemodynamic changes in patients with hypertension under medical treatment following tracheal intubation.

Design

Clinical trial with control group, parallel groups, double blind, randomized with 78 patients

Settings and conduct

Patients with hypertension and candidates for delayed surgery with general anesthesia and endotracheal intubation undergone surgery at Rasoul Akram hospital. Participants were randomly assigned to three groups. Participants and outcome assessors were also unaware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with American Society of Anesthesiologists (ASA) grade 3 and lower. Non-inclusion criteria: emergency surgery; drug abuse; alcohol consumption; all cases of severe intubation; diabetes, heart failure, kidney failure, taking beta blocker; initial dysrhythmia; systolic pressure more than 170 mmHg and diastolic more than 100 mmHg.

Intervention groups

Group A (intravenous lidocaine), Group B (lidocaine transtracheal) and Group C (non-use of lidocaine)

Main outcome variables

Systolic blood pressure; Blood pressure; Heart rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141127020112N10**

Registration date: **2019-09-02, 1398/06/11**

Registration timing: **retrospective**

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

Registration date

2019-09-02, 1398/06/11

Registrant information

Name

Pooya Derakhshan

Name of organization / entity

Birjand Univesity of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-03-21, 1396/01/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2017-03-21, 1396/01/01

Actual recruitment end date

2018-09-22, 1397/06/31

Trial completion date

2019-03-20, 1397/12/29

Scientific title

Comparison the effect of transtracheal lidocaine and intravenous lidocaine on hemodynamic of Patients with hypertension undergoing drug treatment to tracheal intubation

Public title

Effect of transtracheal lidocaine and intravenous

lidocaine on hemodynamic of Patients

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Patients with American Society of Anesthesiologists (ASA) grade 3 and lower
Exclusion criteria:
Emergency surgery Drug abuse Alcohol consumption All cases of difficult intubation Diabetes Heart failure Kidney failure Taking beta blocker Primary dysrhythmia Systolic pressure more than 170 mmHg Diastolic more than 100 mmHg

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **82**
Actual sample size reached: **78**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients were randomly divided into intervention and control groups using a lottery method. As the names of all participants are placed inside the container. The names are drawn out from the container, respectively, and placed in the intervention and control groups. At the end, the papers containing the names are opened and different groups are determined.

Blinding (investigator's opinion)
Double blinded

Blinding description
Participants and outcome evaluators were not aware of the intervention

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Next to Milad Tower, Hemat Highway ,Tehran

City
Tehran
Province
Tehran
Postal code
14496-14535
Approval date
2018-09-23, 1397/07/01
Ethics committee reference number
IR.IUMS.FMD.REC.1397.154

Health conditions studied

1

Description of health condition studied

Hemodynamic changes in patients with hypertension

ICD-10 code

I10

ICD-10 code description

Essential (primary) hypertension

Primary outcomes

1

Description

Blood pressure

Timepoint

After 4 minutes, patients with appropriate endotracheal tube and 30 seconds after intubation were recorded, at 3, 6 and 9 minutes after intubation, blood pressure and heart rate.

Method of measurement

Mercury barometer

2

Description

Heart rate

Timepoint

After 4 minutes, patients with appropriate endotracheal tube and 30 seconds after intubation were recorded, at 3, 6 and 9 minutes after intubation, blood pressure and heart rate.

Method of measurement

Mercury barometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In group A, fentanyl 2 mg/kg and intravenous lidocaine 2% 1.5mg/ kg was injected and anesthetized by thiopental 4 mg/kg and cisatracurium 0.2 mg/kg. Then, 30 seconds after the induction, blood pressure and heart rate were recorded After 4 minutes,

the patient was intubated by an appropriate tracheal tube and 30 seconds after the intubation, blood pressure and heart rate were recorded again, and then, at minutes 3, 6 and 9 after intubation, the patient's blood pressure and heart rate were recorded. In all monitoring registers, any incidence of dysrhythmia was recorded in the ECG.

Category

Treatment - Drugs

2

Description

Intervention group 2: In the group B, fentanyl 2 mg/kg was injected intravenously and anesthetized by thiopental 4 mg/kg and cisatracurium 0.2 mg/kg. Then, 30 seconds after the induction, blood pressure and heart rate were recorded and lidocaine 2% 1.5mg/ kg was injected as transtracheal. After 4 minutes, the patient was intubated by an appropriate tracheal tube and, similar to group A, at specified times, blood pressure and heart rate were recorded. Lidocaine was injected in the both ways 90 seconds before intubation.

Category

Treatment - Drugs

3

Description

Control group: In the group C, the only difference with other groups was the lack of use of lidocaine.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram hospital

Full name of responsible person

Pooya Derakhshan

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Hazrate Rasoole Akram Hospital, Niayesh St, Satarkhan Av, Tehran, IRAN

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Seyyed Abbas Motavallian (Vice Chancellor for Research)

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Iran University of Medical Sciences, Next to Milad tower, Shahid Hemmat Highway

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Web page address

http://vcr.iums.ac.ir/

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Pooya Derakhshan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Latest degree

Specialist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

All individual data of the participants in this study will be shared after unidentifiable individuals

When the data will become available and for how long

The access period will start from 1398 to 1400

To whom data/document is available

Data will be available to researchers working in the university.

Under which criteria data/document could be used

Just for performing research

From where data/document is obtainable

Refer to the responsible person for accessing the data

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

The data will be available one month after the responsible person's approval

Comments