# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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)

**Phone**
+98 56 3234 1410

**Email address**
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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

**Street address**

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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research@iums.ac.ir

**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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## Person responsible for scientific inquiries

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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**

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**