Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison effects of intravenous and local lidocain and remifentanil on hemodynamic changes during tracheal intubatin in hypertensive patients

Protocol summary

Study aim
Anesthetizing epiglottis and vocal cords for prevention of blood pressure elevation after endotracheal intubation in patients with uncontrolled hypertension

Design
Double-blind randomized clinical trial

Settings and conduct
Intervention group 1: Patients receive 1.5 mg per kg diluted lidocaine up to 10 cc for spray with nalton catheter on vocal cords and epiglottis. Intervention group two: Patients receive ten cc of lidocaine 1.5 mg per kgdiluted for intravenous injection. Intervention group three: Patients receive remifentanil 1 µg per kg diluted up to 10 cc for intravenous injection.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients over 18 years, Uncontrolled blood pressure Candidates for elective surgery under general anesthesia with endotracheal tube. Exclusion Criteria: Patients who are hypersensitive to any of the drugs lidocaine or remifentanil, Patients who need rapid sequence induction, mallampati 3,4, difficult intubation, Consumption of beta blocker, Patients who need to receive antihypertensive medication due to a significant increase in blood pressure during surgery.

Intervention groups
Intervention group 1: Patients receive 1.5 mg per kg diluted lidocaine up to 10 cc for spray with nalton catheter on vocal cords and epiglottis. Intervention group two: Patients receive ten cc of lidocaine 1.5 mg per kgdiluted for intravenous injection. Intervention group three: Patients receive remifentanil 1 µg per kg diluted up to 10 cc for intravenous injection.

Main outcome variables
Blood Pressure

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141009019470N116**
Registration date: **2021-04-13, 1400/01/24**
Registration timing: **prospective**

Last update: **2021-04-13, 1400/01/24**
Update count: **0**

Registration date
2021-04-13, 1400/01/24

Registrant information

Name
Farzaneh Masihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 71 3647 4270

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masihif@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-04-18, 1400/01/29

Expected recruitment end date
2021-08-10, 1400/05/19

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison effects of intravenous and local lidocain and remifentanil on hemodynamic changes during tracheal intubatin in hypertensive patients

Public title
Comparison effects of intravenous and local lidocain and remifentanil on hemodynamic changes during tracheal intubatin in hypertensive patients
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Patients over 18 years ASA 2-3 Uncontrolled blood pressure Patients who are candidate for elective surgery under general anesthesia with endotracheal tube
Exclusion criteria:
Patients who are hypersensitive to any of the drugs lidocaine or remifentanil Patients who need rapid sequence induction Mallampati 3,4 Difficult intubation Consumption of beta blocker Patients who need to receive antihypertensive medication due to a significant increase in blood pressure during surgery
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **90**
Randomization (investigator's opinion)
Randomized
Randomization description
By simple randomization and number extraction in triplicate blocks from www.sealedenvelope.com and an anesthesia nurse who has no role in the study will divide patients into three groups one, two and three.
Blinding (investigator's opinion)
Double blinded
Blinding description
Patients do not know the type of group assignment. In order to blind the anesthesiologist who is in charge of collecting data, an anesthesiologist who is aware of the conditions of study and grouping of patients, prepares the drugs and gives them to the anesthesiologist and the anesthesiologist is not aware of the type of drug in the syringe. In all three groups, patients receive an intravenous injection and a topical drug administration to the vocal cords and epiglottis.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street
City
Shiraz
Province
Fars
Postal code
7134844119
Approval date
2020-12-13, 1399/09/23
Ethics committee reference number
IR.SUMS.MED.REC.1399.462

Health conditions studied

1

Description of health condition studied
hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Blood pressure
Timepoint
After endotracheal intubation and after removal
Method of measurement
monitoring

2

Description
Heart rate changes
Timepoint
After endotracheal intubation and after removal
Method of measurement
monitoring

3

Description
آریتمی قلبی
Timepoint
After endotracheal intubation and after removal
Method of measurement
monitoring

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Two similar 10 cc syringes marked with labels A and B. Syringe A containing 1.5 mg / kg lidocaine diluted to 10 cc for spraying with nelaton catheter on the vocal cords and epiglottis and B syringe containing 10 cc Distilled water for intravenous injection.
Category
Prevention

2

Description
Intervention group: Two similar 10 cc syringes marked with labels A and B. Syringe A containing 10 cc of distilled water for spraying with a nalton catheter on the vocal cords and epiglottis and syringe B containing 10 cc of lidocaine 1.5 mg / ml Diluted kg for intravenous injection.
Category
Prevention

3

Description
Intervention group: Two similar 10 cc syringes marked with labels A and B. Syringe A containing 10 cc of distilled water for spraying with a nalton catheter on the vocal cords and epiglottis and syringe B containing remifentanil 1 µg / kg diluted to 10 cc for intravenous injection.
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Khalili Hospital
Full name of responsible person
Nooshin Reza Alizadeh
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
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
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Nushin Reza Alizadeh
Position
Anesthesiology Resident
Latest degree
Medical doctor
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
It is against the policies of our center.
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available