

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 kg diluted 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 kg diluted 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)

##### Phone

+98 71 3647 4270

##### Email address

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 intubation 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

آرتمی 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

##### Street address

Khalili St, Khalili Educational and Medical Center

##### City

Shiraz

##### Province

Fars

##### Postal code

1433671348

##### Phone

+98 71 3629 1470

##### Email

khalili@sums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shiraz University of Medical Sciences

##### Full name of responsible person

Abbas Rezaieanzadeh

##### 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

خیابان زند، طبقه هفت

##### Phone

+98 71 3647 4270

##### Email

vcrd@sums.ac.ir

#### 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

##### Other areas of specialty/work

Anesthesiology

##### Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

##### City

Shiraz

##### Province

Fars

**Postal code**  
7134844119  
**Phone**  
+98 71 3647 4270  
**Email**  
nushin.alizadeh@gmail.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**  
Shiraz University of Medical Sciences  
**Full name of responsible person**  
Seyed Mohammad Hadavi  
**Position**  
Anesthesiologist  
**Latest degree**  
Specialist  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Anesthesiology Department, Faghihi Hospital, Zand Street  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134844119  
**Phone**  
+98 917 123 1237  
**Email**  
Hadavimr@sums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences  
**Full name of responsible person**  
Farzaneh Masihi  
**Position**  
BS in anesthesia/English Consultant  
**Latest degree**  
Master  
**Other areas of specialty/work**  
Anesthesiology  
**Street address**  
Anesthesiology Department, Namazi Hospital, Namazi square  
**City**  
Shiraz  
**Province**  
Fars  
**Postal code**  
7134844119  
**Phone**  
+98 71 3647 4270  
**Email**  
masihifarzaneh@yahoo.com

## 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