

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jun 2026

### Comparison of Lidocaine, Huffing Maneuver and combination of both in prevention fentanil induced cough before induction of anesthesia

#### Protocol summary

##### Study aim

To determine the effect of lidocaine and Huffing maneuver in preventing reflective cough after rapid fentanil injection

##### Design

Prospective randomized controlled clinical trial

##### Settings and conduct

400 Patients in the Namazi Hospital are randomly divided into four groups of each 100. 100 people are considered as control group. First intervention group: Patients receive 2 mg / kg lidocaine before injection of fentanil. Second intervention group: Huffing maneuver is performed for patients before injection of fentanil. Third intervention group: patients received 2 mg / kg lidocaine with Huffing maneuver . Fourth intervention group: Combined protocol (2 mg / kg lidocaine is injected one minute before fentanil injection and after 55 seconds, huffing maneuver is performed after a deep breath less than 5 seconds, and followed by fentanil 2.5 µg/kg and patients are checked every two minutes.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 16 - 65 years old; elective surgery.  
Exclusion criteria: Asthma; Chronic cough; upper respiratory tract infection two weeks before surgery; smoking; steroid therapy; using bronchodilator and ACE inhibitor.

##### Intervention groups

First intervention group: Patients receive 2 mg / kg lidocaine before injection of fentanil. Second intervention group: Huffing maneuver is performed before injection of fentanil. Third intervention group: Injection of 2 mg / kg lidocaine with Huffing maneuver on patients.

##### Main outcome variables

Existence or absence of cough reflex and also the severity of coughing are evaluated. 1-2 coughs grade one, 3-4 coughs grade 2 and 5 and more than 5 coughs considered as grade 3.

#### General information

##### Reason for update

Due to the inconsistency recorded in the date of the Ethical approval code and Forgetting to correct the date, please correct the date.

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141009019470N74**

Registration date: **2018-03-09, 1396/12/18**

Registration timing: **prospective**

Last update: **2021-01-18, 1399/10/29**

Update count: **1**

##### Registration date

2018-03-09, 1396/12/18

##### 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

2018-03-15, 1396/12/24

##### Expected recruitment end date

2018-09-15, 1397/06/24

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Comparison of Lidocaine, Huffing Maneuver and combination of both in prevention fentanil induced cough before induction of anesthesia

### Public title

The relation between Lidocaine and Huffing Maneuver in prevention of cough after fentanil injection

### Purpose

Prevention

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 16 - 65 years old, elective surgery

#### Exclusion criteria:

Asthma; Chronic cough, upper respiratory tract infection two weeks before surgery; smoking; steroid therapy; using bronchodilator and ACE inhibitor.

### Age

From **16 years** old to **65 years** old

### Gender

Both

### Phase

2-3

### Groups that have been masked

- Outcome assessor

### Sample size

Target sample size: **400**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Block randomization

### Blinding (investigator's opinion)

Single blinded

### Blinding description

only observer after intervention is blinded to the study

### Placebo

Not 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

Central Building of Shiraz University of Medical Sciences

##### City

Shiraz

##### Province

Fars

### Postal code

7134844119

### Approval date

2015-03-03, 1393/12/12

### Ethics committee reference number

IR.SUMS.MED.RED.1394.61

## Health conditions studied

### 1

#### Description of health condition studied

The relation between Lidocaine and Huffing Maneuver in prevention of cough after fentanil injection

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Cough reflect

#### Timepoint

2 minutes after fentanil injection

#### Method of measurement

Observation

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control group:

#### Category

N/A

### 2

#### Description

Intervention group:

#### Category

Prevention

### 3

#### Description

Intervention group:

#### Category

Prevention

### 4

#### Description

Intervention group:

#### Category

Prevention

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Namazi Hospital

**Full name of responsible person**

Lale Dehghanpishe

**Street address**

Namazi Suare, Namazi Hospital

**City**

Shiraz

**Province**

Fars

**Postal code**

713484419

**Phone**

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**Email**

masihifarzaneh@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Dr Seed Basir Hashemi

**Street address**

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

**City**

Shiraz

**Province**

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**Postal code**

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**Email**

vcrdep@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**

Fatemeh Bagheri Baravati

**Position**

anesthesiology resident/physician

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

Anesthesiology Department, Faghihi Hospital, Zand Street

**City**

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**Province**

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71937-11351

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masihifarzaneh@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Abdolhamid Chohdri

**Position**

Anesthesiologist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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hameedchohedri@yahoo.com

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Shiraz University of Medical Sciences

**Full name of responsible person**

Farzaneh Masihi

**Position**

MS in English Teaching ,BS in Anesthesia/English  
Consultant

**Latest degree**

Master

**Other areas of specialty/work**

Others

**Street address**

5th floor, Mohammad Rasoul Allah Research Tower,  
Khalili Street

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**Postal code**

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**Phone**

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**Fax****Email**

masihifarzaneh@yahoo.com

**Web page address**

## 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**

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

**Statistical Analysis Plan**

No - There is not 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**

Not applicable

**Analytic Code**

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

**Data Dictionary**

Not applicable