

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### Comparison of intravenous remifentanil and lidocaine on the cardiovascular response to laryngoscopy and tracheal intubation under general anesthesia in open limbs surgery.

#### Protocol summary

##### Study aim

Determination and comparison of the effect of remifentanil with intravenous lidocaine in controlling the cardiovascular response to laryngoscopy and endotracheal intubation in general anesthesia

##### Design

Clinical trial with control group, double-blind, randomized, phase 2 in 60 patients

##### Settings and conduct

Sixty patients were divided into two intervention and control groups by double-blind method and this study was performed in the operating room

##### Participants/Inclusion and exclusion criteria

Open limb surgery under general anesthesia and the risk of one and two anesthesia Cases of difficult intubation and any problems with laryngoscopy and intubation

##### Intervention groups

A group of 30 people received Remy Fentanyl

##### Main outcome variables

Blood pressure Pulse rate

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200501047255N1**

Registration date: **2020-07-27, 1399/05/06**

Registration timing: **retrospective**

Last update: **2020-07-27, 1399/05/06**

Update count: **0**

##### Registration date

2020-07-27, 1399/05/06

##### Registrant information

Name

mohammadtaghi koochaki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3663 6813

##### Email address

mtkzf.ms@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-05-11, 1399/02/22

##### Expected recruitment end date

2020-06-11, 1399/03/22

##### Actual recruitment start date

2020-05-14, 1399/02/25

##### Actual recruitment end date

2020-06-11, 1399/03/22

##### Trial completion date

2020-06-26, 1399/04/06

##### Scientific title

Comparison of intravenous remifentanil and lidocaine on the cardiovascular response to laryngoscopy and tracheal intubation under general anesthesia in open limbs surgery.

##### Public title

Comparison of intravenous remifentanil and intravenous lidocaine in prevention of cardiovascular response following laryngoscopy and tracheal intubation under general anesthesia in limbs surgery.

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

##### Inclusion criteria:

Open limbs surgery under general anesthesia Class 1

and 2 of anesthesia risk (According to American society of anesthesiologist's classification),

**Exclusion criteria:**

Difficult intubation prolonged ( more than 30 seconds) attempts at laryngoscopy Repeated attempts at laryngoscopy

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

**Sample size**

Target sample size: **60**

Actual sample size reached: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Simple blind randomization Which consists of 60 completely identical sheets and is written in 30 sheets of the control group and 30 sheets of intervention and each patient is divided by removing one sheet and the sheet is left out.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

60 identical small ball(30 intervention and 30 control) in a bag used for randomization,for each patient one ball randomly took by anesthetist. patient, researcher and data collector were unaware of patient group.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of Shahroud university of medical sciences

**Street address**

Shahroud university of medical sciences , 7tir sq

**City**

Shahroud

**Province**

Semnan

**Postal code**

36147-73947

**Approval date**

2020-05-09, 1399/02/20

**Ethics committee reference number**

IR.SHMU.REC.1399.042

**Health conditions studied**

1

**Description of health condition studied**

Open reduction and internal fixation of ulna and radius fracture

**ICD-10 code**

S52.4

**ICD-10 code description**

Fracture of shaft of radius

2

**Description of health condition studied**

Open reduction of humerus fracture

**ICD-10 code**

S42.4

**ICD-10 code description**

Fracture of lower end of humerus

3

**Description of health condition studied**

Open reduction of tibia fractures

**ICD-10 code**

S82.3

**ICD-10 code description**

Fracture of lower end of tibia

**Primary outcomes**

1

**Description**

Blood pressure

**Timepoint**

Before induction of anesthesia and just following laryngoscopy and tracheal intubation

**Method of measurement**

Non-invasive blood pressure measurement with Novin Saadat monitor.

2

**Description**

Pulse rate

**Timepoint**

Before induction of anesthesia and just following laryngoscopy and tracheal intubation

**Method of measurement**

Non-invasive blood pressure measurement with Novin Saadat monitor.

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: 30 of participants that received remifentanyl with a dose of 2 µg/kg

#### Category

Treatment - Drugs

### 2

#### Description

Control group: A group of 30 people who received 1.5 micrograms per kilogram of lidocaine weight.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Imam Hossein hospital

##### Full name of responsible person

Javad nourian

##### Street address

End of Ayatollah Towheedi Blvd.

##### City

Shahroud

##### Province

Semnan

##### Postal code

3616911151

##### Phone

+98 23 3234 2001

##### Fax

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##### Email

javadnourian@gmail.com

##### Web page address

<http://shmu.ac.ir/emh/fa>

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

Javad nourian

##### Street address

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##### Province

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##### Email

Javadnourian@gmail.com

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahroud 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

Shahroud University of Medical Sciences

##### Full name of responsible person

Dr Javad nourian

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Shahroud Haft Tir Square Shahroud University of Medical Sciences

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Shahroud University of Medical Sciences

##### Full name of responsible person

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**Position**

Assistant professor

**Latest degree**

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**Other areas of specialty/work**

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahroud University of Medical Sciences

**Full name of responsible person**

Dr Javad nourian

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**City**

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**Province**

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**Postal code**

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**Phone**

+98 23 3239 5054

**Email**

javadnourian@gmail.com

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**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**

No - There is not a plan to make this available

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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