

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jun 2026

### Comparison of inhalational Isoflurane-Nitrous oxide anesthesia and intravenous Propofol-Remifentanyl anesthesia on postoperative pain in open reduction and internal fixation of leg and ankle.

#### Protocol summary

##### Study aim

Comparison of pain scale after the open fracture of leg and ankle between intravenous and inhalation anesthesia

##### Design

Double blind randomized controlled clinical trial with two parallel arms group.

##### Settings and conduct

The research will be performed as a double-blind clinical trial. The investigator and the analyst are not aware of the type of intervention. The sample will consist of 60 patients in the operating room of Shahrud Imam Hossein Hospital. The patients were randomly assigned according to quadruple blocks in two groups (group A or intervention) or (group B or control). In both groups, the patients were kept fast at least 8 hours, and through a safe intravenous line, a pre-anesthetic drug (fentanyl, one microgram per kilogram of weight) will be prescribed. Initiation of anesthesia is performed by injection of Propofol 2mg / kg and muscle relaxation with atracurium 0.5 mg / kg and intracranial intubation. In the intervention group, the anesthetic continues to be as follows: Remifentanyl 0.25 µg / kg / min + Propofol 150 µg / kg / min equivalent to 60 ml propofol 1% per hour and 20 ml remifentanyl per hour (50 µg / ml concentration). A patient with 50% oxygen will be ventilated. In the control group, anesthesia with nitrous oxide with oxygen (50% N<sub>2</sub>O / 50% O<sub>2</sub>) and isoflurane (1.2% - 1.5%) would be continued in both. The study is conducted at Imam Hossein Shahrud Hospital.

##### Participants/Inclusion and exclusion criteria

Arrival: Female or Male Age between 18 until 60 ASA class 1,2 Patients with open fractures of leg & ankle  
Exclusion: Drug abuse & opiate, History of anticonvulsions or antidepressant therapy, Anesthesia or surgery complications

##### Intervention groups

Intervention: Propofol -Remifentanyl intravenous anesthesia  
Control: Inhalation Isoflurane -nitrous oxide anesthesia

##### Main outcome variables

pain, dose of the pethidine after operative

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170130032313N1**

Registration date: **2018-06-08, 1397/03/18**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-06-08, 1397/03/18**

Update count: **0**

##### Registration date

2018-06-08, 1397/03/18

##### Registrant information

##### Name

**Name of organization / entity**

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 4422 0262

##### Email address

niloofar.kh71@shmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-05-23, 1397/03/02

##### Expected recruitment end date

2018-07-21, 1397/04/30

##### Actual recruitment start date

empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of inhalational Isoflurane-Nitrous oxide anesthesia and intravenous Propofol-Remifentanil anesthesia on postoperative pain in open reduction and internal fixation of leg and ankle.

**Public title**  
The effect of nitrous oxide inhaled isoferons on postoperative pain "The effect of Remifentanil propofol on postoperative pain

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Male or female Age between 18 until 40 ASA class 1,2  
Patients with open fractures of leg & ankle

**Exclusion criteria:**

A history of drug use and drug abuse Anticonvulsant intake, sedative, anti-depressant Any complications that change the procedure and anesthesia

**Age**

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

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**

Target sample size: **60**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

According to randomized quadruple blocks, researcher gives a predetermined series of 60 A and B cards to the anesthetist and based on this pattern participants will assign in to either intervention (A) or control (B) group. After the examination of the patient, After examination of the patient, anesthetist gives information about this study to every participant that has inclusion criteria,, removes an envelope in the order specified (blind concealment) and based on the envelope, group A and B is determined. Researcher and analyst before the end of the study are not aware of the type of intervention in the two groups A and B and and only the type of the group is recorded in the questionnaire.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The patient is unaware of his grouping. The analysis and analysis of the consequences are done by unknown scholars of grouping. The questionnaire consists of two

parts, each containing both parts of a single code. After the anesthetic, the section containing the patient's demographic information is separated and the patient will record the outcome of the postoperative pain in the second part.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

1

**Ethics committee**

**Name of ethics committee**

Ethics committee of shahrud university of medical sciences

**Street address**

Shahrud university of medical science, Haftetir Squard

**City**

Shahrud

**Province**

Semnan

**Postal code**

۳۶۱۴۷-۷۳۹۴۷

**Approval date**

2016-11-09, 1395/08/19

**Ethics committee reference number**

IR.SHMU.REC.1395.122

**Health conditions studied**

1

**Description of health condition studied**

Postoperative pain intensity in candidal patients for open leg and ankle surgery

**ICD-10 code**

**ICD-10 code description**

**Primary outcomes**

1

**Description**

Pain score with NRS questionnaire

**Timepoint**

2,4,6 hours after transfer of the ward then every 6 hours within 24 hours

**Method of measurement**

NRS questionnaire

**Secondary outcomes**

## 1

### Description

Dose of pethidine prescribed

### Timepoint

2,4,6 hours after transfer to ward then every 6 hours within 24 hours

### Method of measurement

NRS questionnaire

## Intervention groups

## 1

### Description

In both groups, the patients are kept at least 8 hours fasting and prescribed by a safe line prior to anesthesia (fentanyl, one microgram per kilogram of weight). Anesthesia starts with Propofol injection of 2mg / kg and muscle relaxation with 0.5 mg / kg atracurium injections. Then, anesthesia is performed in the intervention group: Remifentanyl 0.25 µg / kg / min + Propofol 150 µg / kg / min, which is equivalent to 60 ml propofol 1% per hour and 20 ml remifentanyl per hour (concentration 50 µg / ml). The patient will be ventilated with 50% oxygen. In the control group, anesthesia with nitrous oxide with oxygen (50% O<sub>2</sub> / 50% N<sub>2</sub>O) and isoflurane (1.5%-1.2%) will continue to be carried out in both groups of cardiovascular and respiratory monitoring And the depth of anesthesia will be adjusted according to the clinical symptoms. Muscle promoter can be repeated in both groups. In recovery, pethidine pain will be given at a dose of 20 mg. After transfer to the unit, if pethidine is present, it will be prescribed 20 mg every 6 hours.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

Imam Hussein Hospital

#### Full name of responsible person

Niloofar Khoobestani

#### Street address

Imam Hossein hospital, Operating room, End of Ayatollah Towhidi avenue

#### City

Shahrud

#### Province

Semnan

#### Postal code

36169-11151

#### Phone

+98 21 4422 0262

#### Email

niloofar.kh71@yahoo.com

#### Web page address

<http://eh.shmu.ac.ir>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Shahrud University of Medical Sciences

#### Full name of responsible person

Mohammad Hasan Emamian

#### Street address

Deputy of research; Shahrud university of medical sciences, 7th of Tlr Square

#### City

Shahrud

#### Province

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+98 23 3239 5054

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#### Email

emamian@shmu.ac.ir

#### Web page address

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

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Shahrud 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

Shahrud University of Medical Sciences

#### Full name of responsible person

Niloofar Khoobestani

#### Position

Medical intern

#### Latest degree

Medical doctor

#### Other areas of specialty/work

General Practitioner

#### Street address

بلوار مرزداران- خیابان فرشتگان- فرشته ۲- پلاک ۷- زنگ ۱

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#### Province

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## Person responsible for scientific inquiries

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**Web page address**  
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## Person responsible for updating data

### Contact

**Name of organization / entity**

Shahroud University of Medical Sciences  
**Full name of responsible person**  
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**Latest degree**  
Medical doctor  
**Other areas of specialty/work**  
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شهر Tehran  
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**Province**  
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**Phone**  
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**Email**  
niloofar.kh71@yahoo.com  
**Web page address**  
<http://shmu.ac.ir/research/fa>

## 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

All of the writers dont agree with it

### 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