Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

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.

Protocol summary

Study aim

Comparison of pain scale after the open fracture of leg and ankele between intravenus 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 Remifentanil 0.25 µg / kg / min + Propofol 150 µg / kg / min equivalent to 60 ml propofol 1% per hour and 20 ml remifentanil 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% N2O / 50% O2) and isoflurane (1.2% - 1.5%) would be continued in both The study is conducted at Imam Hossein Shahroud 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 antidepressent therapy, Anesthesia or surgery complications

Intervention groups

Intervention: Propoful -Remifentanyl intravenous anesthesia Control:Inhalation Isoflurane -nitrosoxide anesthesia

Main outcome variables

pain, dose of the pethedine 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 sience, 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: Remifentanil 0.25 µg / kg / min + Propofol 150 µg / kg / min, which is equivalent to 60 ml propofol 1% per hour and 20 ml remifentanil 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% O2 / 50% N2O) 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
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Imam Hossein hospital,Operating room, End of Ayatollah Towhidi avenue
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
Mohammmad Hasan Emamian
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Deputy of research;Shahrud university of medical sciences,7th of TIr Square
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Fax
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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
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
Niloofar Khoobestani
Position
Medical intern
Latest degree
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Other areas of specialty/work
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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
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