

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of intravenous propofol-remifentanyl anesthesia and inhalational isoflurane-remifentanyl anesthesia on QTc interval in patients receiving methadone maintenance therapy who are candidate for open limbs surgery.

Protocol summary

Study aim

Comparison of intravenous propofol-remifentanyl anesthesia and isoflurane inhalational anesthesia on QTc interval in patients receiving methadone maintenance therapy who are candidate for open limbs surgery

Design

Double blind randomized clinical trial, Sixty participants with inclusion criteria after justification and informed concern assign in intervention or control group.

Settings and conduct

This study performs in operation rooms of Imam Hossein Hospital, . Anesthesiologist and nurse anesthesia are aware of patient's group and record in questionnaire. Questionnaire has two portion (demographic and data recording portion) with identical cod. They separate data recording portion and gives it to person who is responsible of outcome recording and is unaware of patient grouping.(syringes pump and isoflurane vaporizer have covers)Data analysig investigator is also unaware of patient's grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Male, Age 18 - 60 Methadone maintenance therapy with a dose of at over 50 mg per day Open limbs surgery under general anesthesia Class 1 and 2 of anesthesia risk Exclusion criteria: Use of every drug except methadone in last week Moderate and severe systemic disorders(anesthesia risk over 2) Every preoperative abnormal heart rate and rhythm. Need for injection of any drug out of study protocol

Intervention groups

Intervention group: Maintenance of anesthesia performs with Intravenous propofol-remifentanyl (propofol 100 g / kg / min with remifentanyl 1 microgram / kg / min) And the dose of the propofol will be adjusted based on the depth of anesthesia. Control group: Maintenance of anesthesia performs with inhalational isoflurane and

intravenous remifentanyl (1.2% isoflurane and 1 microgram/kg/min remifentanyl).The dose of isoflurane will be adjusted based on the depth of anesthesia.

Main outcome variables

QT interval

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200524047560N1**

Registration date: **2021-01-02, 1399/10/13**

Registration timing: **registered_while_recruiting**

Last update: **2021-01-02, 1399/10/13**

Update count: **0**

Registration date

2021-01-02, 1399/10/13

Registrant information

Name

Javad Amiri

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-09-22, 1399/07/01

Expected recruitment end date

2021-01-04, 1399/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous propofol-remifentanyl anesthesia and inhalational isoflurane-remifentanyl anesthesia on QTc interval in patients receiving methadone maintenance therapy who are candidate for open limbs surgery.

Public title

Comparison of propofol intravenous anesthetic and Isoflurane inhalational anesthetic on QTc interval in ECG of patients receiving methadone maintenance therapy who are candidate for open limbs surgery.

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Male Age 18 - 60 Methadone maintenance therapy with a dose of at over 50 mg per day Open limbs surgery under general anesthesia Class 1 and 2 of anesthesia risk (According to American society of anesthesiologist's classification) Normal preoperative heart rate and rhythm

Exclusion criteria:

Use of every drug except methadone in last week Moderate and severe systemic disorders(anesthesia risk over 2) Every abnormal heart rate and rhythm Need for injection of a drug that changes routine anesthesia protocol.

Age

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

Gender

Male

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

After informed concern participants, according quadruple blocks randomization assigns to control or intervention group. Sixty envelope (30 of them with letter A=Intervention and other 30 envelop with letter B= control based on the randomization table is provided and for each participant corresponding envelope is given to the anesthesiologist by person who is responsible for randomization. Anesthetist, records the group's type in participant's questionnaire and then the envelope is left

out.

Blinding (investigator's opinion)

Double blinded

Blinding description

Anesthesiologist and nurse anesthesia are aware of patient's group and this group is recorded in questionnaire by them. Questionnaire has two portion with identical cod. Nurse anesthesia separates data recording portion and gives it to person who is responsible of outcome recording and is unaware of patient grouping. (syringes pump and isoflurane vaporizer have cover.)

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, 7th of Tir Square - Shahroud University of Medical Sciences and Health Services

City

Shahroud

Province

Semnan

Postal code

36147-73947

Approval date

2020-11-30, 1399/09/10

Ethics committee reference number

IR.SHMU.REC.1399.121

Health conditions studied**1****Description of health condition studied**

Open reduction and internal fixation of limbs under general anesthesia in methadone maintenance treatment patients.

ICD-10 code

S52.4

ICD-10 code description

Fracture of shaft of radius

Primary outcomes**1****Description**

QT interval
Timepoint
Preoperative - 20 minutes after induction of anesthesia -
After recovery
Method of measurement
Record of lead_2 of electrocardiogram

2

Description
Pulse rate
Timepoint
Preoperative - 20 minutes after induction of anesthesia -
After recovery
Method of measurement
Record of lead_2 of electrocardiogram

Secondary outcomes

1

Description
Corrected QT
Timepoint
Preoperative- 20 minutes after induction of anesthesia-
end of recovery
Method of measurement
QTc calculator software using QT and pulse rate

Intervention groups

1

Description
Intervention group: 30 men between the ages of 18 and 60 undergoing maintenance treatment with a minimum dose of 50 mg daily of methadone requiring surgery and under intravenous anesthesia propofol-remifentanyl (propofol 100 g / kg / min with remifentanyl 1 g / kg / min) And the dose of the drug will be adjusted based on the depth of anesthesia. In this study we use from propofol (Claris Lifescience limited, India by Daya darou Co.), Isoflurane (Primal critical care inc. USA by Exir Co.) and Remifentanyl (GSK by Jahan behbood Co.).
Category
Treatment - Drugs

2

Description
Control group: 30 men between the ages of 18 and 60 undergoing maintenance therapy with a minimum dose of 50 mg daily of methadone who require surgery and will undergo isoflurane-remifentanyl inhalation anesthesial (Isoflurane 1.2% with remifentanyl 1 microgram /kg/min) and the dose of isoflurane will be adjusted based on the depth of anesthesia. In this study we use from propofol (Claris Lifescience limited, India by Daya darou Co.), Isoflurane (Primal critical care inc. USA by Exir Co.) and Remifentanyl (GSK by Jahan behbood Co.).
Category

Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
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
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Position
Assistant Professor
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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

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

Yes - There is 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

Title and more details about the data/document

Informed consent form will be obtained from each patient before the operation. All information can be published after identifying individuals.

When the data will become available and for how long

After completing the research and data analysis

To whom data/document is available

All researchers are interested

Under which criteria data/document could be used

Researchers whose identity is documented and who intend to use research information scientifically

From where data/document is obtainable

Dr. javad nourian - - javadnourian@gmail.com - 0098 912
173 1359 javad amiri - javadamiri94@gmail - 0098 938
155 6473

What processes are involved for a request to access data/document

1. The researcher requests research information and

data by email and sending documents of scientific degrees and documents. 2. After reviewing the individual information, the research data will be provided to the control groups after identifying them and intervening.

Comments