Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of intravenous propofol-remifentanil anesthesia and inhalational isoflurane-remifentanil 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-remifentanil 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 seperate 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-remifentanil (propofol 100 g / kg / min with remifentanil 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 remifentanil (1.2% isoflurane and 1 microgram/kg/min remifentanil).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

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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-remifentanil anesthesia and inhalational isoflurane-remifentanil 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-remifentanil (propofol 100 g / kg / min with remifentanil 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 Remifentanil (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-remifentanil inhalation anesthesial (Isoflurane 1.2% with remifentanil 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 Remifentanil (GSK by Jahan behbood Co.).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Hossein Educational and Research Center

Full name of responsible person

Javad Nourian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahroud University of Medical Sciences

Full name of responsible person

Dr. Mohammad Hasan Emamian

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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

Javad Nourian

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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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