

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

Comparative study of intravenous injection of methadone and sufentanil on hemorrhage in patients with opioid addiction under cardiopulmonary bypass surgery

Protocol summary

Study aim

Comparative study of intravenous injection of methadone and sufentanil on hemorrhage in patients with opioid addiction under cardiopulmonary bypass surgery

Design

This study is a double-blinded clinical trial. The study population will include all patients undergoing bypass surgery who will refer to the Imam Ali hospital in Kermanshah city. A total of 159 eligible patients will be selected conveniently and randomly assigned to three groups (two intervention and one control group)

Settings and conduct

This study, which will be done at Imam Ali hospital of Kermanshah city is double-blinded, that patients and researchers are unaware of the study groups, the type of drug and the dose of the drug. At the beginning of the study, the rate of bleeding in each of the three groups is recorded in a checklist

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with opioid addiction; Patients undergoing bypass surgery. Exclusion criteria: Having any history of coagulation disorder; Systolic blood pressure above 160 and less than 100; Renal failure patients

Intervention groups

The first intervention group will receive 0.5 mg/kg of methadone at a dose of 0.5-2 mg, during and after surgery in ICU. The second intervention group will receive 3 µg of sufentanil at a dose of 5-10 µg during and after surgery in ICU. The control group will receive 0.5 mg of placebo

Main outcome variables

The rate of bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130812014333N103**

Registration date: **2018-10-06, 1397/07/14**

Registration timing: **registered_while_recruiting**

Last update: **2018-10-06, 1397/07/14**

Update count: **0**

Registration date

2018-10-06, 1397/07/14

Registrant information

Name

Feizollah Foroughi

Name of organization / entity

kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1821 4653

Email address

froughi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-09-16, 1397/06/25

Expected recruitment end date

2018-10-22, 1397/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of intravenous injection of methadone

and sufentanil on hemorrhage in patients with opioid addiction under cardiopulmonary bypass surgery

Public title

Comparison of intravenous injection of methadone and sufentanil on hemorrhage in patients with opioid addiction under cardiac surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with opioid addiction Patients undergoing bypass surgery

Exclusion criteria:

Having any history of coagulation disorder Systolic blood pressure above 160 and less than 100 Renal failure patients

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **159**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomly Individually by random number table via code receipt

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the patients and the investigator will kept blinded to the study groups, the type of drug and the dose of the drug

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2018-09-11, 1397/06/20

Ethics committee reference number

ir.kums.rec.1397.418

Health conditions studied

1

Description of health condition studied

Coronary Artery Disease

ICD-10 code

I25.1

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

The rate of bleeding

Timepoint

During the operation and in the I.C.U

Method of measurement

Based on observation doctor

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 0.5 mg/kg of methadone at a dose of 0.5-2 mg, during and after surgery in ICU

Category

Treatment - Drugs

2

Description

. The second intervention group will receive 3 µg of sufentanil at a dose of 5-10 µg during and after surgery in ICU

Category

Treatment - Drugs

3

Description

The control group will receive 0.5 mg of placebo

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Ali Hospital

Full name of responsible person

Fatemeh Rangani

Street address

Imam Ali Hospital, Shahid Beheshti Blvd.

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Postal code

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Phone

+98 83 3836 0041

Email

shimarangani@YAHOO.COM

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti

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fnajafi@kums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kermanshah 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

Kermanshah University of Medical Sciences

Full name of responsible person

Fatemeh Rangani

Position

Residents anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Gholamreza Moradi

Position

Faculty Member of Kermanshah University of Medical Sciences

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Imam Ali Hospital, Shahid Beheshti Blvd.

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Drmoradi2008@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Kermanshah University of Medical Sciences

Full name of responsible person

Fatemeh Rangani

Position

Residents anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

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

Title and more details about the data/document

The main outcomes of the study will be shared.

When the data will become available and for how long

2months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

En In a 30-day period, the documents will be sent e-mail

Comments