

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Clinical trial of the effect of intravenous analgesia by fentanyl compared to ketamine in patients undergo coronary heart bypass surgery

Protocol summary

Summary

Objective: Clinical trial of the effect of intravenous analgesia by fentanyl compared to ketamine in patients undergo coronary heart bypass surgery. Design of the study: randomization using random permuted blocks, convenience sampling, double-blind, single-center, phase II trial. Study population: all patients with stage 5 of renal failure. Main inclusion criteria: pre-operation ejection fraction above 30%; class one to three of ASA; no simultaneous heart valves involvement; no need of intra-aortic pump usage during the operation. Main exclusion criteria: positive history of sensitivity to study drugs; uncontrolled systemic disease such as diabetes; addiction to alcohol and drugs; positive history of psychologic disease and depression; asthma and other hypersensitivity reactions; intraoperative fracture of sternum and ribs; pre-operative liver enzymes rising higher than two folds; other chest pain causes other than coronary arteries; presence of neurologic signs and symptoms; any type of consciousness impairment pre-operation. Sample size: 160. Interventions: First group: Bolus intravenous infusion of 50 microgram fentanyl followed by pump infusion of 5 to 50 microgram per cc in speed in hour; second group: bolus intravenous infusion of 0.5 milligrams per kilogram of ketamine followed by pump infusion of 0.5 milligrams per kilogram in hour. Intervention time: after the operation and before being transferred to ICU.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017041233381N1**

Registration date: **2017-05-08, 1396/02/18**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-05-08, 1396/02/18

Registrant information

Name

Marziye Yousefi

Name of organization / entity

Zahedan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.yousefi@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zahedan University of Medical Sciences

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of the effect of intravenous analgesia by fentanyl compared to ketamine in patients undergo coronary heart bypass surgery

Public title

Comparison the effect of intravenous analgesia by fentanyl versus ketamine in patients undergo coronary heart surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Main inclusion criteria: pre-operation ejection fraction above 30%; class one to three of ASA; no simultaneous heart valves involvement; no need of intra-aortic pump usage during the operation. Main exclusion criteria: positive history of sensitivity to study drugs; uncontrolled systemic disease such as diabetes; addiction to alcohol and drugs; positive history of psychologic disease and depression; asthma and other hypersensitivity reactions; intraoperative fracture of sternum and ribs; pre-operative liver enzymes rising higher than two folds; other chest pain causes other than coronary arteries; presence of neurologic signs and symptoms; any type of consciousness impairment pre-operation.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 160

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Zahedan University of Medical Sciences

Street address

Ethics Committee of Zahedan University of Medical Sciences, Zahedan University of Medical Sciences, Dr.Hesabi Square, Zahedan

City

Zahedan

Postal code

Approval date

2017-02-19, 1395/12/01

Ethics committee reference number

IR.ZAUMS.REC.1395.95

Health conditions studied

1

Description of health condition studied

Coronary artery surgery

ICD-10 code

I25, I25.0

ICD-10 code description

Atherosclerotic heart disease

Primary outcomes

1

Description

Postoperation pain

Timepoint

Two heures, four heures, eight heures, 12 heures and 24 heures after surgery

Method of measurement

VAS Criteria

2

Description

Mean arterial pressure

Timepoint

Up to 24 hours after surgery in intervals of every 4 hours

Method of measurement

Millimeter of mercury

3

Description

Heart rate

Timepoint

Up to 24 hours after surgery in intervals of every 4 hours

Method of measurement

Beats in minute

Secondary outcomes

empty

Intervention groups

1

Description

First group: Bolus intravenous infusion of 50 micrograms fentanyl followed by pump infusion of 5 to 50 micrograms per cc in speed in hour

Category

Treatment - Drugs

2

Description

Second group: bolus intravenous infusion of 0.5 millirograms per kilogram of ketamine followed by pump infusion of 0.5 millirograms per kilogram in hour.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ali-ebn Abi Taleb Hospital, Zahedan

Full name of responsible person

Marziye Yousefi

Street addressOperation room, Zahedan Ali-ebn Abi Talib Hospital,
Salamat Blvd, Dr.Hesabi Sq., Zahedan**City**

Zahedan

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Vice chancellor for research, Zahedan University of
Medical Sciences**Full name of responsible person**

Mohsen Taheri

Street addressVice chancellor for research, Zahedan University of
Medical Sciences, Zahedan**City**

Zahedan

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding sourceVice chancellor for research, Zahedan University of
Medical Sciences**Proportion provided by this source**

100

Public or private sector*empty***Domestic or foreign origin***empty***Category of foreign source of funding***empty***Country of origin****Type of organization providing the funding***empty***Person responsible for general inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Marziye Yousefi

Position

Anesthesiology Residence

Other areas of specialty/work**Street address**Operation room, Ali-ebn Abi Taleb Hospital, Salamat
Blvd, Dr.Hesabi Sq., Daneshgah Ave., Zahedan**City**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Zahedan University of Medical Sciences

Full name of responsible person

Maziyar Mahjoubi Fard

Position

Cardiac Anesthesia Fellowship

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Full name of responsible person

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Position

Anesthesiology Residence

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Fax**Email****Web page address**

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty