Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 millirograms per kilogram of ketamine followed by pump infusion of 0.5 millirograms 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

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Name of organization / entity
Zahedan University of Medical Sciences
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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 houres, four houres, eight houres, 12 houres and 24 houres 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 address
Operation 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 address
Vice 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 source
Vice 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
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Person responsible for updating data

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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