

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Sep 2026

Comparison of fentanyl pump analgesia (PCA) with the combination of morphine, ketamine and lidocaine on pain after coronary artery bypass grafting (CABG)

Protocol summary

Study aim

Comparison of fentanyl pump analgesia (PCA) with the combination of morphine, ketamine and lidocaine on pain after coronary artery bypass grafting (CABG) in Shahid Mohammadi Hospital in Bandar Abbas During in 2024

Design

A comparative, double-blind, randomized clinical trial, phase 2 on 60 patients, rand function of Excel software was used for randomization.

Settings and conduct

After surgery, patients will be transferred to the ICU under full care. Patients will be randomly divided into two groups. The first group, the group receiving fentanyl (500 mcg in a diluted solution of 100 cc of distilled water at a rate of 4 cc per hour) and the second group, the group receiving morphine (20 mg), ketamine (20 mg) and lidocaine (200 mg) at a rate of 4 cc per hour with a pain pump. Also, the demographic characteristics of the patients (age, gender, weight and height) were recorded in the researcher-made questionnaire by the anesthesiologist who was not aware of the type of intervention and the patient's condition and pca pump. It should be noted that pain relief pumps do not contain any information about the drug or drugs used in the research.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidates for elective CABG surgery Patients 30-80 years old Anesthesia class II, III exclusion criteria: Pump time more than 120 minutes Simultaneous valve and CABG ,Emergency surgery

Intervention groups

The intervention group includes patients who are candidates for CABG surgery who receive fentanyl analgesia pump after the operation The intervention group includes patients who are candidates for CABG surgery, who receive the combined analgesia pump of

morphine, ketamine and lidocaine after the operation.

Main outcome variables

systolic blood pressure' diastolic blood pressure'mean arterial pressure:nausea and vomiting rate ' average patient pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231227060539N1**

Registration date: **2024-01-28, 1402/11/08**

Registration timing: **prospective**

Last update: **2024-01-28, 1402/11/08**

Update count: **0**

Registration date

2024-01-28, 1402/11/08

Registrant information

Name

Iman Zafarasoodeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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izawlm72@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-20, 1403/01/01

Expected recruitment end date

2025-03-20, 1403/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of fentanyl pump analgesia (PCA) with the combination of morphine, ketamine and lidocaine on pain after coronary artery bypass grafting (CABG)

Public title

Investigating the effect of fentanyl with the combination of morphine, ketamine and lidocaine in pain after open heart surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidates for elective CABG surgery Patients 30-80 years old Anesthesia class II, III Not receiving painkillers within 6 hours before surgery surgeryConsent to participate in the study EF > 40% Patients without a history of renal, hepatic, gastrointestinal, or pulmonary failure No alcohol or drug addiction

Exclusion criteria:

Pump time more than 120 minutes Simultaneous valve and CABG CABGReoperation to control bleeding and progressive heart failure (requiring high dose postoperative inotropes or IABP) Emergency surgery

Age

From **30 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description

After the operation, the patient goes to the ICU, neither the patient nor the resident knows about the syringe pump drugs.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of hormozgan university of medical sciences

Street address

Hormozgan university of medical sciences. Blo. Shahid chamran. Bandar Abbas

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bandar abbas

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1388579166

Approval date

2024-01-24, 1402/11/04

Ethics committee reference number

IR.HUMS.REC.1402.393

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

Heart failure

ICD-10 code

I50.4

ICD-10 code description

Combined systolic (congestive) and diastolic (congestive) heart failure

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

Measurement of pain score in patients undergoing cabg

Timepoint

Pain score in hours 1, 2, 6, 12 after cabg patients

Method of measurement

Numeric rating scale for pain

Secondary outcomes**1****Description**

The level of patient satisfaction

Timepoint

1, 2, 6, 12 hours after surgery

Method of measurement

Visual analogue scale

2**Description**

Average systolic blood pressure

Timepoint

1,2,6,12 hours after surgery

Method of measurement

Blood pressure cuff

3

Description

Average diastolic blood pressure

Timepoint

1,2,6,12 hours after surgery

Method of measurement

Blood pressure cuff

4

Description

Average mean arterial pressure

Timepoint

1,2,6,12 hours after surgery

Method of measurement

Blood pressure cuff

5

Description

Average heart rate

Timepoint

1,2,6,12 hours after surgery

Method of measurement

Chest lead monitoring

6

Description

Average pain of patients

Timepoint

1,2,6,12 hours after surgery

Method of measurement

Numeric rating scale

Intervention groups

1

Description

The first intervention group, the group receiving fentanyl(Caspian Pharmaceutical Company) (500 mcg in a diluted solution of 100 cc of distilled water at a rate of 4 cc per hour)

Category

Treatment - Drugs

2

Description

The second intervention group received morphine (Aborehan pharmaceutical company) (20 mg), ketamine (Elixir pharmaceutical company) (20 mg) and lidocaine (Caspian pharmaceutical company) (200 mg) in a diluted solution of 100 cc Distilled water at a speed of 4 cc per hour with the pump.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid mohammadi hospital

Full name of responsible person

Iman Zafar Asoodeh

Street address

Shahid Mohammadi Hospital,Jomhoori Eslami St,Emam Khomeini St,Bandar Abbas

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr hashem jari neshin

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Hormozgan University Of Medical Sciences,BLO Shahid Chamran,Bandar ABBas

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Web page address

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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

Bandare-abbas 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

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sdkashani486@gmail.com

Person responsible for general inquiries**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Doctor Saiid Kashani

PositionAssociate Professor, Department of Anesthesiology,
Hormozgan University of Medical Sciences**Latest degree**

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

Bandare-abbas University of Medical Sciences

Full name of responsible person

Iman Zafar Asoodeh

Position

Anesthesiologist resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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

Bandare-abbas University of Medical Sciences

Full name of responsible person

Doctor Hashem Jari Neshin

PositionProfessor of the Department of Anesthesiology,
Hormozgan University of Medical Sciences**Latest degree**

Subspecialist

Other areas of specialty/work

Anesthesiology

Street addressShahid Mohammadi Hospital,Jomhoori Eslami
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Bandar Abbas

Province

Hormozgan

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

Not applicable

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/documentAll information of intervention patients can be shared
after de-identification**When the data will become available and for how long**The access period starts 6 months after the results are
published**To whom data/document is available**

Researchers working in academic and scientific institutions

Under which criteria data/document could be used

The conditions are as follows: People related to clinical groups Inclusion of my name and colleagues in the desired research

From where data/document is obtainable

Email lzawlm72@gmail.com Iman zafar Asoodeh

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

After sending the email and checking the request, the response will be done within 48 hours

Comments