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)
Phone
+98 76 3334 5009
Email address
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
City
bandar abbas
Province
Hormozgan
Postal code
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 (Caspin 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

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Phone

+98 76 3334 7000

Fax

+98 76 3333 3280

Email

lzawlm72@gmail.com

Web page address

http://shmh.hums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bandare-abbas University of Medical Sciences

Full name of responsible person

Dr hashem jari neshin

Street address

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

City

Bandar Abbas

Province

Hormozgan

Postal code

7916613885

Phone

+98 76 3333 3280

Fax

+98 76 3333 3280

Email

Info@hums.ac.ir

Web page address

https://www.hums.ac.ir

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

Person responsible for general inquiries

Contact
Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Doctor Saiid Kashani
Position
Associate Professor, Department of Anesthesiology, Hormozgan University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Mohammadi Hospital,Jomhoori Eslami St,Emam Khomeini St,Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 76 3334 7000
Fax
+98 76 3333 3280
Email
sdkashani486@gmail.com

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
Position
Professor of the Department of Anesthesiology, Hormozgan University of Medical Sciences
Latest degree
Subspecialist
Other areas of specialty/work
Anesthesiology
Street address
Shahid Mohammadi Hospital,Jomhoori Eslami St,Emam Khomeini St,Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 76 3334 7000
Fax
+98 76 3333 3280
Email
sdkashani486@gmail.com

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
Street address
Shahid Mohammadi Hospital,Jomhoori Eslami St,Emam Khomeini St,Bandar Abbas
City
Bandar Abbas
Province
Hormozgan
Postal code
7916613885
Phone
+98 76 3334 7000
Fax
+98 76 3333 3280
Email
Izawlm72@gmail.com

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/document
All 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 Izawlm72@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