

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of the use of morphine bolus and using a portable infusion pumps for pain management in patients after coronary artery bypass grafting surgery (CABG)

Protocol summary

Summary

Pain control in patients after coronary artery bypass surgery is the purpose of this study. Sixty eight patients (aged 30-65 years), with 3-vessel disease (3VD), ejection fraction greater than 40% who undergone coronary artery bypass surgery using a heart-lung pump will be entered in the study. One mg oral Lorazepam at the night before surgery and 1 hour before transfer to the operating room and 1 mg/kg intramuscular morphine half an hour before transfer to the operating room given to patients for sedation. All patients underwent coronary artery bypass grafting surgery with the same technique using heart-lung pump arranged. After surgery, patients transferred to cardiac intensive care with tracheal tube and underwent to mechanical ventilation. Patients separate from ventilator and the endotracheal tube is removed between 6-8 hours. Then, patients divide into two equal groups after extubation. For patients in group P, PCA pump containing 3 ampoules of morphine is equivalent to 30 mg infused with speed of 0.02 mg/kg/h. In group M, 0.03 mg/kg bolus morphine given to patients with VPS>3 and repeated 3 times in 1 hour if pain not controlled. Group M will receive infusion of normal saline as placebo. If pain is not controlled after administration of morphine in two groups, intravenous Apotel and Diclofenac suppository are used. In both groups, every 2 hours for 12 hours and then every 4 hours to 24 hours, vital signs including blood pressure and heart rate, pain on the VPS score (Verbal pain scale) and the incidence of complications such as hypoxia, sedation and gastrointestinal effects assessed and recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012814359N3**

Registration date: **2015-04-24, 1394/02/04**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-24, 1394/02/04

Registrant information

Name

Vally Imantalab

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1666 9064

Email address

vimantalab@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2015-04-30, 1394/02/10

Expected recruitment end date

2015-11-05, 1394/08/14

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the use of morphine bolus and using a portable infusion pumps for pain management in

patients after coronary artery bypass grafting surgery (CABG)

Public title

Pain control after coronary artery bypass grafting surgery (CABG)

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Patients aged 30-65 years;Three vessels disease (3VD) Exclusion criteria:Patients not extubated after 8 hours;Patients requiring reoperation for bleeding ;Patients with advanced heart failure (requiring high-dose postoperative inotropic or need to put intra-aortic balloon pump (IABP)

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **68**

Randomization (investigator's opinion)

Randomized

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

Not blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

Block Randomization

Secondary Ids

empty

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

Ethics committee of Guilan University of Medical Sciences

Street address

Shahid Beheshti Freeway

City

Rasht

Postal code

4193833697

Approval date

2015-01-05, 1393/10/15

Ethics committee reference number

1930474204

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**

Pain

Timepoint

Every 2 hours for 12 hours and then every 4 hours to 24 hours

Method of measurement

Using verbal pain score (VPS).0-10

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention 1: Infusion 30 mg morphine sulfate 10 mg/cc with speed of 0.02 mg/kg/h using PCA pump up to 24 hours

Category

Treatment - Drugs

2**Description**

Intervention 2: Injection 0.03 mg/kg bolus morphine sulfate 10 mg/cc three time in one hour up to 24 hours

Category

Treatment - Drugs

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

Heshmat Hospital

Full name of responsible person

Valli Imantalab

Street address

Fifteenth Khordad Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

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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

Vice chancellor for research of Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Vali Imantalab

Position

Anesthesiologist

Other areas of specialty/work**Street address**

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Person responsible for updating data

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Medical laboratory Sciences Technician/ Bachelor's Degree

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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