

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect and comparison of oral and intravenous Acetaminophen in pain control and Consumption opioid in post cardiac surgery patients

Protocol summary

Summary

The aim of this study is to evaluate the effect of oral and injectable acetaminophen for pain control after cardiac surgery. Study design randomly. The study population is all patients will be undergoing cardiac surgery at the Madani hospital Khormmabad. Such as the inclusion criteria to participate in this study, all patients undergoing CABG surgery with or without valve replacement. Also who have no history of addiction to drugs and alcohol as well as renal and hepatic failure. Such as the exclusion criteria of this study, the patient's pain score greater than 7 and not wanting to continue cooperation. The sample size for each group of 40 people and all sample 160 people was calculated. Available sampling will be done using four blocks. Patients in group A received acetaminophen injection every 6 hours, and if continues pain will be administered pethedine. Patients in group B if have pain will be received acetaminophen injection, and if continues pain will be administered pethedine. Patients in group C patients received oral acetaminophen every 6 hours, and if continues pain will be administered pethedine. Patients in group D if have pain will be received oral acetaminophen, and if continues pain will be administered pethedine. Start time the study that patients were extubated and are fully alert and awake. For assessment of pain will be used visual analog scale. Pain at the time of 0, 20, 80, 120 minutes after receiving the first dose and during deep breathing and coughing, will be checked. The level of pain and opioid consumption in the four groups will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016022026217N2**

Registration date: **2016-03-16, 1394/12/26**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2016-03-16, 1394/12/26

Registrant information

Name

Sajad Yarahmadi

Name of organization / entity

Iran University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 66 3322 5655

Email address

yarahmadi.s@tak.iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Lorestan University of Medical Sciences

Expected recruitment start date

2016-09-06, 1395/06/16

Expected recruitment end date

2017-02-04, 1395/11/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect and comparison of oral and intravenous Acetaminophen in pain control and Consumption opioid in post cardiac surgery patients

Public title

The effect and comparison of oral and intravenous Acetaminophen in pain cardiac surgery patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients who underwent CABG surgery with or without valve replacement; age older than 18 or less than 65 years; absence of addiction to drugs or alcohol; absence of allergy or hypersensitivity to acetaminophen or narcotics; absence of impaired kidney function (creatinine level Less than 2 milligrams per deciliter); no history of liver failure; no history of sleep apnea. Exclusion criteria: Visual analog scale score is higher than 7 after extubation; not wanting to continue cooperation; use of narcotic drugs and sedatives during the procedure; decreased level of consciousness of the patient during the study.

Age

From **18 years** old to **65 years** old

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)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Selected by sampling and random assignment method.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Lorestan University of Medical Sciences

Street address

km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences

City

Khoramabad

Postal code

Approval date

2015-11-25, 1394/09/04

Ethics committee reference number

LUMS.REC.1394.41

Health conditions studied

1

Description of health condition studied

Coronary and valvular heart surgery

ICD-10 code

I97.1

ICD-10 code description

Other functional disturbances following cardiac surgery

Primary outcomes

1

Description

Amount of pain

Timepoint

Minute 0, 20, 80 and 120 after receiving the first dose

Method of measurement

visual analog scale

2

Description

The amount of narcotic

Timepoint

24 hours after receiving the first dose

Method of measurement

Milligrams per kilogram of body weight

Secondary outcomes

1

Description

The best pattern of use drug on regular basis or on when necessary

Timepoint

24 hours after receiving the first dose

Method of measurement

Visual analog scale and milligrams per kilogram of body weight

2

Description

Nausea

Timepoint

frequency during the first 24 hours after receiving the first dose

Method of measurement

history taking from patient or nurses

3

Description

Vomiting

Timepoint

frequency during the first 24 hours after receiving the first dose

Method of measurement

4**Description**

need for antiemetics

Timepoint

frequency during the first 24 hours after receiving the first dose

Method of measurement

information taken from patient's records

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

Patients in group A received acetaminophen injection every 6 hours, and if continues pain will be administered pethedine.

Category

Treatment - Drugs

2**Description**

Patients in group B if have pain will be received acetaminophen injection, and if continues pain will be administered pethedine.

Category

Treatment - Drugs

3**Description**

Patients in group C received oral acetaminophen every 6 hours, and if continues pain will be administered pethedine.

Category

Treatment - Drugs

4**Description**

Patients in group D if have pain will be received oral acetaminophen, and if continues pain will be administered pethedine.

Category

Treatment - Drugs

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

Center of Cardiology shahid Ayatollah Madani

Full name of responsible person

Sajad Yarahmadi

Street address

Ayatollah Madani Heart Hospital, Boulevard Kheirabad

City**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research, Lorestan University of Medical Science

Full name of responsible person

Morovat Taheri Kalani

Street address

km 5 Road of Khorram Abad - Boroujerd - opposite to the Kahrizak village- Integrated Lorestan Medical Sciences

City

Khorramabad

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, Lorestan University of Medical Science

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**

Lorestan University Of Medical Sciences

Full name of responsible person

Sajad Yarahmadi

Position

Intensive Care Nursing Graduate Student

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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

Person responsible for updating data

Contact

Name of organization / entity

Lorestan University Of Medical Sciences

Full name of responsible person

Sajad Yarahmadi