Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of paracetamol and ketorolac on pain management in patients with non-synthetic opium abuse undergoing off pump Coronary artey bypass grafting

Protocol summary

Study aim

the objective of the study is to compare efficacy and complications of intravenous paracetamol and ketorolac for pain management of opium abusers undergoing CABG.

Design

In this RCT 100 patients with non-synthetic opium abuse scheduled for elective off-pump CABG are randomly (based on randomization number table) assigned to receive either paracetamol(n=50) or ketorolac (n=50).

Settings and conduct

The study will be conducated at postcardiac surgery ICU at Emam Reza hospital, Mashhad, Iran. In patients under mechanical ventilation, pain is assessed using CPOT score hourly. After weaning, NRS is used for pain evaluation every hour in the first 24 hours and every 4 hours on the second day. In case of pain, fentanyl 0.5 and 1 µg/kg every hour is used for for CPOT 3-5, and 6-8, respectively. Pain scores and fentanyl requirements are recorded and compared in the first and second 24 hours. Frequency of AKI and GI complications are explored. The patients, investigator, and data analyzers are blinded to the study.

Participants/Inclusion and exclusion criteria

adult patients with non-synthetic opium abuse undergoing elective CABG are recruited for the study. Patients with history of renal, gastrointestinal, or hepatic diseases, or bleeding are excluded from the study.

Intervention groups

The patients in the acetaminophen group will receive the drug 15 mg/kg at maximum 1 gram intravenously every 6 hours for 24 hours. The patients in the ketorolac group will receive the drug 0.5 mg/kg at maximum 60 mg intravenously every 6 hours for 24 hours.

Main outcome variables

pain score; amount of additional analgesic; frequency of AKI and GI complications

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150216021098N5**
Registration date: **2018-04-19, 1397/01/30**
Registration timing: **prospective**

Last update: **2018-04-19, 1397/01/30**
Update count: **0**

Registration date

2018-04-19, 1397/01/30

Registrant information

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Shahram Amini
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Mashhad University of Medical Sciences
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-12-22, 1397/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of the effect of paracetamol and ketorolac on pain management in patients with non-synthetic opium abuse undergoing off pump Coronary artey bypass grafting

Public title
Comparison of paracetamol and ketorolac on pain management in patients with opium abuse undergoing cardiac surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Adult older than 18 years undergoing off-pupm CABG ASA class 2 or 3 Non-synthetic opium abuse

Exclusion criteria:
Allergy to either of drugs Consumption of either drugs in the past 48 hours Preoperative use of nephrotoxic drugs Presence of renal insufficiency or plasma creatinine higher than 1.3 mg/dL History of gastrointestinal disease or bleeding, peptic ulcer, perioperative bleeding Hepatic insufficiency Ejection fraction less than 40% Postoperative need for intraaortic ballon pump perioperative hemodynamic compromise Unwanter intraoperative events including arrhythmia or cardiac arrest refusal to stay in the study

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
The patients are randomly assigned to either group using randomization numbers table and will receive the intervention accordingly.

Blinding (investigator's opinion)
Triple blinded

Blinding description
After explaining the study method, interventions, and the administered drugs, the participants in either pararcetamol or ketorolac group, the outcome assessor, and the data analyzer will be blind to the administered drug. The patients do not know which drug is going to be used. The outcome assessors do not know which drug is going to be used. The data analyzer does not know which drug is going to be used.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Mashhad University of Medical Sciences, Daneshgah street

City
Mashhad

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Razavi Khorasan

Postal code
9791733135

Approval date
2017-12-13, 1396/09/22

Ethics committee reference number
IR.MUMS.fm.REC.1396.198

Health conditions studied

1

Description of health condition studied
Coronary artery bypass grafting

ICD-10 code
T82

ICD-10 code description
Complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description
Pain intensity

Timepoint
every one and four hours in the first and second days, respectively after intervention

Method of measurement
Observation (CPOT0 and questioning (NRS) scores

Secondary outcomes

1

Description
Additional analgesic requirement

Timepoint
every one hour on the first day and every 4 hours on the second day

Method of measurement

Recording the amount of administered fentanyl in microgram

2

Description
Frequency of acute kidney injury
Timepoint
Every day after intervention until discharge from the hospital
Method of measurement
AKIN criteria

3

Description
Frequency of gastrointestinal bleeding and discomfort
Timepoint
every day after intervention until discharge from the hospital
Method of measurement
Observation and questioning

Intervention groups

1

Description
Intervention group 1: In the paracetamol group, the patients receive the drug 15 mg/kg at maximum 1 gram intravenously every 6 hours after arrival at ICU for 24 hours.
Category
Treatment - Drugs

2

Description
Intervention group 2: In ketorolac group, the patients receive the drug 0.5 mg/kg at maximum 60 mg intravenously every 6 hours after arrival at ICU for 24 hours
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
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Sponsors / Funding sources

1

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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
Mashhad 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
Maragheh University of Medical Sciences
Full name of responsible person
Shahram Amini
Position
Profesor of anesthesiology and critical care
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available