Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of effect of paracetamol on post-operative pain in coronary artery bypass graft surgery

Protocol summary

Summary

Aim of this study was determination of the effect of intravenous paracetamol on perioperative pain severity in coronary artery bypass graft surgery. Coronary artery bypass graft surgery candidates, enrolled in the study. They excluded from study because of excessive post-operative bleeding. The study population was patients that had referred to Isfahan Chamran Heart Hospital for cardiac surgery. Sample volume was 110 patients that randomly divided in to two blank and trial groups (n=55) This clinical trial was prospective, randomized, triple-blind, placebo-controlled and single-center. In paracetamol group: 15 minutes before induction of anesthesia and then every 6 hours for 3 days, 1 g paracetamol in 50 ml normal saline was infused in a 15-minute. In control group we use normal saline instead of paracetamol in all stages of study in the same volume. The pain severity after surgery was evaluated based on two criteria, Facial analgesia scale and Visual analgesia scale at rest and after taking a deep breath.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015101613181N2**
Registration date: **2015-11-17, 1394/08/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-11-17, 1394/08/26

Registrant information

Name

Mojtaba Mansouri

Name of organization / entity

Isfahan university of medical sciences

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Recruitment status

Recruitment complete

Funding source

Isfahan university of Medical Sciences

Expected recruitment start date

2014-05-31, 1393/03/10

Expected recruitment end date

2015-07-31, 1394/05/09

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of effect of paracetamol on post-operative pain in coronary artery bypass graft surgery

Public title

Evaluation of the Effect of intravenous paracetamol on perioperative pain in coronary artery bypass graft surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion Criteria: Inclusion criteria for the study were: undergoing elective surgery CABG, the individual agreement to participate in the study, age 40 to 70 years, not having liver failure (Serum bilirubin greater than 1.8 mg per deciliter and aspartate and alanine aminotransfraz more than 1.5 times of the upper limit of normal), not having renal failure (serum creatinine

greater than 2 mg per deciliter), not addictive to opioid drugs and psychotropic substances, and having cardiac ejection fraction greater than 30%., Exclusion criteria for the study: Excessive bleeding after surgery (more than 150 ml for the first two hours), having other surgeries in addition to coronary artery bypass surgery such as repair or replacement of heart valves, repeated surgery, and the need for aortic balloon support.

Age
From **40 years** old to **70 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **110**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
IsfahanUniversity of Medical Sciences

Street address
Hezar Jarib st.

City
Isfahan

Postal code

Approval date
2013-08-20, 1392/05/29

Ethics committee reference number
393595

Health conditions studied

1

Description of health condition studied
Perioperative pain

ICD-10 code
T82.8

ICD-10 code description
Other specified complications of cardiac and vascular prosthetic devices, implants and grafts

Primary outcomes

1

Description
pain

Timepoint
during study

Method of measurement
VAS and FAS

Secondary outcomes

empty

Intervention groups

1

Description
In paracetamol group 15 minutes before induction of anesthesia 1 g intravenous paracetamol in 50 cc normal saline solution was infused to the patient within 15 minutes. Next dose of paracetamol was 1 g which was infused intravenously over 15 minutes within 6-4 hours after the first dose, so that the injection time was during the last 20 minutes of surgery. Then subsequent doses of paracetamol, every 6 hours for 3 days was injected in intensive care at a rate of 1 g.

Category
Prevention

2

Description
In the control group at all stages of paracetamol injection instead of paracetamol equal volume of normal saline was used.

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Chamran Heart Hospital

Full name of responsible person
Mojtaba Mansouri

Street address
Chamran Heart Hospital

City
Isfahan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Isfahan University of Medical Sciences
Full name of responsible person
Research Department
Street address
Isfahan University of Medical Sciences
City
Isfahan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Isfahan 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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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