Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Effect of Paracetamol and Ketorolac on pain management after cardiac surgery in children

Protocol summary

Summary

Purpose: Clinical trial comparing effect of Paracetamol and Ketorolac on pain management after cardiac surgery in children. Design and criteria: This study is prospective, randomized and double blinded clinical trial. Researchers and patient were blind about the type of drugs. Patients in this study were randomly divided into two groups. In group 1 (n=40) to reduce pain was used Paracetamol a dose of 15 mg per kg every 6 hours for 48 hours, and in group 2 (n=40) to reduce pain was used ketorolac 0.5 mg per kg every 6 hours for 48 hours. Inclusion criteria: All patients undergoing cardiac surgery; children between the age of 12-2 years. Exclusion criteria: patient dissatisfaction; addiction; drug allergy. Ketorolac groups: patients with renal insufficiency. Paracetamol group having allergies; liver failure; renal failure. Intervention group 1 : Paracetamol as commercial name Apotel made by Couble drug company with dose of 15 mg per kg every 6 hours was used for 48 hours. Intervention group 2 : Ketorolac intravenous with dose of 0.5 mg every 6 hours made by Exir company was used for 48 hours. Primary outcome 1 : Pain. Primary outcome time point: Every 1 hour to 24 hours after the second day every 4 hours for 48 hours Primary outcome method of measurement: CPOT (Critical-care Pain Observation Tool)

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015012320759N1**
Registration date: **2015-09-15, 1394/06/24**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-09-15, 1394/06/24

Registrant information

Name
Ghasem Soltani
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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+98 51 3852 5209
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soltanigh@mums.ac.ir

Recruitment status

Recruitment complete

Funding source
Vice Chancellor for Research, Mashhad University of Medical Science

Expected recruitment start date

2014-08-06, 1393/05/15

Expected recruitment end date

2015-02-09, 1393/11/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Paracetamol and Ketorolac on pain management after cardiac surgery in children

Public title

Clinical trial comparing effect of Paracetamol and Ketorolac on pain management after cardiac surgery in children

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria: All patients undergoing cardiac surgery; children between the age of 12-2 years.

Exclusion criteria: patient dissatisfaction; addiction; drug allergy. Ketorolac groups: patients with renal insufficiency. Parecetamol group having allergies; liver failure; renal failure

Age

From **91 years** old to **81 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

City

Mashhad

Postal code

Approval date

2014-07-26, 1393/05/04

Ethics committee reference number

930142

Health conditions studied

1

Description of health condition studied

Precordial pain

ICD-10 code

R07.2

ICD-10 code description

Precordial pain

Primary outcomes

1

Description

Pain

Timepoint

Every 1 hour to 24 hours after the second day every 4 hours for 48 hours

Method of measurement

CPOT (Critical-care Pain Observation Tool)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1 : Paracetamol as commercial name Apotel made by Couble drug company with dose of 15 mg per kg every 6 hours was used for 48 hours.

Category

Treatment - Drugs

2

Description

Intervention group 2 : Ketorolac intravenous with dose of 0.5 mg per kg every 6 hours made by Exir company was used for 48 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Ghasem Soltani

Street address

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Science

Full name of responsible person

Hamid Eslami

Street address

Ghoreishi apartment, Daneshgah street, Mashhad

City

Mashhad

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, Mashhad 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

Mashhad University of Medical Science

Full name of responsible person

Dr Ghasem Soltani

Position

Associate Professor

Other areas of specialty/work

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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