Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the effect sole paracetamol for pain control after knee arthroscopy surgeries

Protocol summary

Summary

Objectives: This study is aimed to assess of the effect sole paracetamol for pain control after knee arthroscopy surgeries. Design: Prospective randomized clinical trial. Setting and conduct : Tertiary regional and teaching hospital. Participants including major eligibility criteria: Fifty patients, with age 15-60yr; ASA Class I- II, undergoing knee arthroscopy surgeries in Akhtar hospital during 2014-2015,were included . Patients were randomized into two groups of 25 each, using a table of random numbers. Intervention: Study group, patients received paracetamol 2 g IV infusion over 15 minutes every 6 hours for 24 hours. control group, patients received morphine in morphine Patient-controlled analgesia (PCA) pump, at the request of the patient 1 mg/ mL bolus with a minimum interval of 6 min. Main outcome measures (variables): Postoperative pain The drug study are coded and delivered to the patients by and individual not aware of the research process. A blind stuff was coded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013112415515N1**
Registration date: **2014-09-23, 1393/07/01**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2014-09-23, 1393/07/01

Registrant information

Name

Masoud Hashemi

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2261 2252

Email address

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Expected recruitment start date

2014-09-01, 1393/06/10

Expected recruitment end date

2014-09-21, 1393/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect sole paracetamol for pain control after knee arthroscopy surgeries

Public title

The effect of paracetamol for pain control after knee arthroscopy surgeries.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Age 15-60 yr;ASA Class I- II; Arthroscopic knee surgery under epidural anesthesia. Exclusion criteria: Taking any pain medication 24 hours before surgery; Patients unable or unwilling to use patient-controlled analgesia (PCA); Liver failure; Kidney failure; Severe cardiopulmonary; Coagulopathy; Obesity morbid; History of postoperative nausea and vomiting;

History of migraine; History of complications during and after surgery; Postoperative complications in the first 24 hours that may require intervention; Known allergies; Sensitivity or contraindication for opioid and non opioid drugs; Pregnancy and lactation; Substance abuse.

Age
From **78 years** old to **33 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **50**

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
Shahid Beheshti University of Medical Sciences

Street address
Tabnak S.

City
Tehran

Postal code

Approval date
2014-08-17, 1393/05/26

Ethics committee reference number
92/11/10 /432/ر

Health conditions studied

1

Description of health condition studied
Acute pain management after knee arthroscopy

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Pain score

Timepoint
Arrival in the recovery room, 15 and 30 min, 1, 2, 4, 6, 12, 18 and 24 hours after study drug administration.

Method of measurement
Visual analog scale

Secondary outcomes

1

Description
Patient satisfaction

Timepoint
First 24 hours after surgery

Method of measurement
Based on the patient's questions

2

Description
Amount of analgesia used

Timepoint
First 24 hours after surgery

Method of measurement
Based on the patient's questions

3

Description
Side effect

Timepoint
First 24 hours after surgery

Method of measurement
Based on the patient's questions

4

Description
Nausea and vomiting

Timepoint
Arrival in the recovery room, 15 and 30 min, 1, 2, 4, 6, 12, 18, 24 h after initiation of study drug

Method of measurement
Based on the score of 1-4

5

Description
Sedation score

Timepoint
Arrival in the recovery room, 15 and 30 min, 1, 2, 4, 6, 12, 18, 24 h after initiation of study drug

Method of measurement
Ramsay scale

Intervention groups

1

Description
In the study group, Intravenous infusion of 2 g paracetamol
Category
Prevention

2

Description
In the control group, Morphine PCA pump
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar Hospital
Full name of responsible person
Masoud Hashemi MD.
Street address
Sharifimanesh Ave., Romi Bridge, Shariati Ave.
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Shahid Beheshti University of Medical Sciences
Full name of responsible person
Mohammad Rahmati Roodsari MD
Street address
Parvaneh St., Yaman St., Shahid Chamran Expressway
City
Tehran
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, Shahid Beheshti 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
Akhtar Hospital
Full name of responsible person
Seyed Masoud Hashemi MD.
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Person responsible for updating data

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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