

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Comparison of the effect of oral gabapentin with a dose of intravenous acetaminophen on pain after knee arthroplasty

Protocol summary

Study aim

Comparison of oral gabapentin effect with a dose of intravenous acetaminophen on pain after knee arthroplasty

Design

Clinical trial with control group and two groups of interventional, double-blind, , 15 cases and three groups is assessed.

Settings and conduct

The present study is a double-blind study that is conducted in Ghaem Hospital in Mashhad, and patients and evaluates are unaware.

Participants/Inclusion and exclusion criteria

After approval by the Ethics Committee and approval of the plan at the University Research Committee, all patients with complete knee arthroplasty were enrolled in the study.

Intervention groups

Intervention group 1: Intravenous injection of 1000 mg intravenous acetaminophen within half an hour during surgery Intervention group 2: Use 600 mg oral gabapentin two hours before surgery

Main outcome variables

Patients' pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190430043424N1**

Registration date: **2019-05-12, 1398/02/22**

Registration timing: **registered_while_recruiting**

Last update: **2019-05-12, 1398/02/22**

Update count: **0**

Registration date

2019-05-12, 1398/02/22

Registrant information

Name

Mohammad Alipour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 5209

Email address

alipourm1398@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-17, 1398/01/28

Expected recruitment end date

2020-03-20, 1399/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of oral gabapentin with a dose of intravenous acetaminophen on pain after knee arthroplasty

Public title

Comparison of the effect of oral gabapentin with a dose of intravenous acetaminophen on pain after knee arthroplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Physical grade I or II in ASA Lack of sensitivity to Gabapentin The absence of mental disorders Do not drink alcohol, drugs, and taking constipation, and

corticosteroids and anticonvulsants on a regular basis or in the past twenty four hours No pregnancy No myasthenia grave disease Not having any kidney disease

Exclusion criteria:
The occurrence of any surgical complications during surgery Reduce or increase the average blood pressure (MAP) Heart rate is greater than 30% of the initial rate

Age
From **18 years** old to **75 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **15**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is a double-blind that the name of the drug is in closed envelopes, and the patients and the investigator are not aware of the type of drug.

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
Department of Anesthesiology, Imam Reza Hospital, Square Taghiabad

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913316

Approval date
2018-12-18, 1397/09/27

Ethics committee reference number
IR.MUMS.MEDICAL.REC.1397.753

Health conditions studied

1

Description of health condition studied

Knee arthroplasty

ICD-10 code

T84.9

ICD-10 code description

Unspecified complication of internal orthopaedic prosthetic device, implant and graft

Primary outcomes

1

Description

Drug measurements

Timepoint

after intervention

Method of measurement

MORPHIN EQUIVALENT

Secondary outcomes

1

Description

Pain

Timepoint

after intervention

Method of measurement

Visual Analogue Scale

Intervention groups

1

Description

Intervention group1: Infusion of 1000 milligrams of intravenous acetaminophen during the first half-hour during surgery

Category

Treatment - Drugs

2

Description

Intervention group: assumption of 600 mg oral gabapentin two hours before surgery

Category

Prevention

3

Description

Control group: No drugs

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ghaem Hospital

Full name of responsible person

Dr. Mohammad Alipour

Street address

Ghaem Hospital, Ahmad Abad Ave

City

Mashhad

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Email

alipourm@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

International Office Administration Center(Qoreishi Building) ; Daneshgah St.,

City

Mashhad

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13944-91388

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+98 51 3841 2081

Email

ramresearch@mums.ac.ir

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

Mashhad University of Medical Sciences

Full name of responsible person

Mohammad Alipour

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan

Not applicable
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
Data file
When the data will become available and for how long
6 months after publication
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
Statistical analyzes are permitted in overview articles on delivered data
From where data/document is obtainable
Send an email to alipourm@mums.ac.ir
What processes are involved for a request to access data/document
6 months after publication
Comments