

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### Comparing the effect of preoperative oral Gabapentin with single dose intravenous Acetaminophen on postoperative pain of knee arthroplasty

#### Protocol summary

##### Study aim

Comparing the effect of preoperative oral Gabapentin with single dose intravenous Acetaminophen on postoperative pain of knee arthroplasty

##### Design

Randomised, controlled, superiority, parallel group trial with a sample size of 90 patients.

##### Settings and conduct

Place: Qaem hospital in Mashhad. Patients are assigned to three groups using randomization software and envelopes. In the first group, 1000 mg of intravenous acetaminophen with the Apotel brand diluted in 100 cc of normal saline and marked with a blue color label is infused during the first half hour during surgery, and the second group is given 600 mg of gabapentin orally with 100 cc water two hours before the operation. The third group, which is the control group, does not receive any medication. During the follow-up period, patients receive painkillers if they have grade four and higher grade pain.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Age between 18-75 years, physical status I or II in ASA (American Society of Anesthesiology), no allergy to gabapentin, absence of mental disorders, not using of alcohol, narcotics, painkillers, corticosteroids and anticonvulsant drugs regularly or in last twenty-four hours.

##### Intervention groups

Intervention group1: Infusion of 1000 milligrams of intravenous acetaminophen during the first half-hour during surgery. Intervention group 2: Assumption of 600 mg oral gabapentin two hours before surgery. Control group: No drugs.

##### Main outcome variables

Primary outcome: Drug measurements; Secondary outcome: Pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100920004780N12**  
Registration date: **2023-09-05, 1402/06/14**  
Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**

Update count: **0**

##### Registration date

2023-09-05, 1402/06/14

##### Registrant information

##### Name

Mohammad Alipour

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 51 1801 2612

##### Email address

alipourm@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-07, 1402/07/15

##### Expected recruitment end date

2024-10-06, 1403/07/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparing the effect of preoperative oral Gabapentin with single dose intravenous Acetaminophen on

postoperative pain of knee arthroplasty

### Public title

Comparing the effect of preoperative oral Gabapentin with single dose intravenous Acetaminophen on postoperative pain of 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: **90**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Simple randomization. Allocation concealment method is sealed envelopes system. Patients are assigned to three groups using randomization software and sealed envelopes.

### 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

science

### Street address

Department of Anesthesiology, Imam Reza hospital, Daneshgah street, Mashhad

### 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 surgery

#### ICD-10 code

T84.9

#### ICD-10 code description

Unspecified complication of internal orthopedic 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

Qaem hospital

#### Full name of responsible person

Mohammad Alipour

#### Street address

Anesthesia department, Qaem hospital, Ahmad-Abad street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9176699199

#### Phone

+98 51 3840 0001

#### Email

alipourm@mums.ac.ir

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Mashhad University of Medical Sciences

#### Full name of responsible person

Majid Ghayourmobarhan

#### Street address

Deputy of research and technology, Qoreshi building, Daneshgah street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9138813944

#### Phone

+98 51 3841 1538

#### Email

ghayourm@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

#### Street address

Anesthesia department, Qaem hospital, Ahmad-Abad street

#### City

Mashhad

#### Province

Razavi Khorasan

#### Postal code

9137913316

#### Phone

+98 51 3852 5209

#### Email

alipourm@mums.ac.ir

## Person responsible for scientific 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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**Province**  
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**Postal code**  
9137913316  
**Phone**  
+98 51 3852 5209  
**Email**  
alipourm@mums.ac.ir

## Person responsible for updating data

### 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  
**Street address**  
Anesthesia department, Qaem hospital, Ahmad-Abad street  
**City**  
Mashhad  
**Province**  
Razavi Khorasan  
**Postal code**  
9137913316  
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+98 51 3852 5209  
**Email**  
alipourm@mums.ac.ir

## 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

Yes - There is a plan to make this available

### 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

All data can be shared after patients are made unidentifiable.

### When the data will become available and for how long

Data can be accessible 6 months after results are published.

### 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

After sending a request email to the corresponding author, data will be sent in one month.

### Comments