# 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**
Mohammd 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 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

**Phone**

+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**