

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

03 Jul 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 evaluators 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

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

+98 51 3852 5209

**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 Offic Administration Center(Qoreishi Building) ; Daneshgah St.,

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

13944-91388

**Phone**

+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

**Street address**

Ghaem Hospital, Taghiabad Square

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**Phone**

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## Person responsible for scientific inquiries

### Contact

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Mashhad University of Medical Sciences

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Mohammad Alipour

**Position**

Associate professor

**Latest degree**

Specialist

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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**