

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

07 Jul 2026

### Comparison of the effect of gabapentin with placebo in reducing acute pain in patients with renal colic referred to Sina Hospital emergency department

#### Protocol summary

##### Study aim

Evaluation of the effectiveness of gabapentin in the control of renal colic pain Evaluation of the effectiveness of gabapentin in reducing opioid use in controlling acute renal colic pain

##### Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 3 on 80 patients. Excel software rand function is used for refinement.

##### Settings and conduct

Among number of patients who referred to the emergency department of Sina Hospital in Tehran due to renal colic pain, after examining the inclusion and exclusion criteria, one group is given 30 mg of ketorolac with 600 mg of gabapentin and the other group is given 30 mg of ketorolac with placebo.(Students and caregivers are blind)The severity of pain at the time of admission and after every 5 minutes is assessed by visual analogue scale. If the pain is severe and the patient's condition is normal, 0.05mg/kg of Morphine is added to the treatment as a rescue until the patient's pain falls below 5.

##### Participants/Inclusion and exclusion criteria

Entry requirements : Patients aged 18-85 years with moderate to severe acute renal colic pain; Obtaining informed written consent from the patient Exit conditions: Patients with: History of severe kidney failure; History of moderate to severe liver failure; History of allergic reactions to gabapentin or its formulation components; Consumption of pregabalin and gabapentin during the last week Intolerance to food; Dissatisfaction with entering the study; Unknown lung disease or history of lung failure in the field of COPD or fibrosis of the lung

##### Intervention groups

We have two intervention groups. Intervention group 1: Gabapentin group (600 mg) which contains two 300 mg gabapentin capsules. Second intervention group: placebo

group which contains two capsules of flour.

##### Main outcome variables

How long it takes to control pain, pain at discharge, and the sum of the need for drugs

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20200322046833N2**

Registration date: **2021-05-22, 1400/03/01**

Registration timing: **registered\_while\_recruiting**

Last update: **2021-05-22, 1400/03/01**

Update count: **0**

##### Registration date

2021-05-22, 1400/03/01

##### Registrant information

##### Name

Farhad Najmeddin

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 6695 4709

##### Email address

f-najmeddin@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-05-22, 1400/03/01

##### Expected recruitment end date

2021-11-22, 1400/09/01

##### Actual recruitment start date

empty

**Actual recruitment end date**  
empty

**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of gabapentin with placebo in reducing acute pain in patients with renal colic referred to Sina Hospital emergency department

**Public title**  
Evaluation of the effectiveness of gabapentin in the control of renal colic pain

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**  
**Inclusion criteria:**  
Patients aged 18-85 years with moderate to severe acute renal colic pain Obtaining informed written consent from the patient  
**Exclusion criteria:**  
History of severe kidney failure History of moderate to severe liver failure History of allergic reactions to gabapentin or its formulation components Consumption of pregabalin and gabapentin during the last week Intolerance to food Dissatisfaction with entering the study History of unknown lung disease or history of pulmonary insufficiency in COPD or fibrosis of the lung

**Age**  
From **18 years** old to **85 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**  
Target sample size: **80**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
Randomization is done by block randomization method, with block size of 8. As we have 5 blocks of 8 as follows: aaaabbbb .1 aaabbbba .2 aabbaabb .3 aabbabab .4 abababab .5 And 80 patient cases that will be divided into 10 groups of 8. Each of these groups will be randomly assigned the number one of the blocks and then we will act based on training a and b of that block for the patient. (a and b are one drug group and the other is a placebo group to which the student is blind)

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, participants and students, as clinical caregivers and outcome assessors, are blind. Gabapentin capsules are placed in larger capsules and the empty space is filled with flour. Placebo capsules are similar to the capsules of the drug group, but are filled with flour.

The names a and b are then randomly assigned to the capsule bag of the drug and placebo, and only the researcher will know the nature of the drug or the placebo a and b.

**Placebo**  
Used

**Assignment**  
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of Tehran university of medical sciences

##### Street address

Tehran university of medical sciences, Enghelab Ave, Enghelab square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۱۷۶۱۴۴۱۱

#### Approval date

2021-01-11, 1399/10/22

#### Ethics committee reference number

IR.TUMS.TIPS.REC.1399.154

## Health conditions studied

### 1

#### Description of health condition studied

Acute renal colic pain

#### ICD-10 code

N23

#### ICD-10 code description

Unspecified renal colic

## Primary outcomes

### 1

#### Description

The average pain intensity at 4 o'clock

#### Timepoint

Measurement of pain intensity at the time of patient admission and then every 5 minutes after drug administration and finally 4 and 8 hours after drug administration

#### Method of measurement

Ask the patient how much pain using the Visual Analogue Scale method

## Secondary outcomes

### 1

#### Description

The average amount of morphine consumed in each group

#### Timepoint

At the time of the patient's arrival and every 5 minutes after the drug is administered, morphine is added to the treatment as rescue if the pain is severe (pain above 7 out of 10).

#### Method of measurement

Sum of the amount of morphine consumed from the moment of arrival until the patient is discharged

### 2

#### Description

Mean pain control time

#### Timepoint

From the moment the patient arrives until discharge

#### Method of measurement

From ketorolac injection to pain control below 5, no narcotics (at least 3 hours after the last narcotics) or discharge

## Intervention groups

### 1

#### Description

Intervention group: Ketorolac with a dose of 30 mg and gabapentin from Mehr Daroo Pharmaceutical Company, two capsules with a dose of 300 mg and morphine with a dose of 0.05 mg per kg by titration method

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Ketorolac with a dose of 30 mg, placebo two capsules containing flour and morphine with a dose of 0.05 mg per kg by titration method

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Sina hospital

##### Full name of responsible person

Farhad Najmeddin

##### Street address

Sina hospital, Hassan-abad square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

113746911

##### Phone

+98 21 6104 0000

##### Email

hosp\_sina@sina.tums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Tehran University of Medical Sciences

##### Full name of responsible person

Farhad Najmeddin

##### Street address

Tehran University of Medical Sciences Research Center, Enghelab Ave, Enghelab square, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

1417614411

##### Phone

+98 21 4291 1000

##### Email

tumspr@tums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Tehran 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

Tehran University of Medical Sciences

##### Full name of responsible person

Farhad Najmeddin

##### Position

Assistant Professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Medical Pharmacy

**Street address**

Sina hospital pharmacy, Hassan-abad square, Tehran

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۱۳۶۷۴۶۹۱۱

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**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

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**Position**

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**Latest degree**

Subspecialist

**Other areas of specialty/work**

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**Person responsible for updating data****Contact****Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Farhad Najmeddin

**Position**

Assistant Professor

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+98 21 6312 1402

**Email**

farhad.najm@gmail.com

**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**

Clinical results will be published through an original article and All other data will be available on request

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

Up to 5 years after publishing the clinical results

**To whom data/document is available**

Researchers and ethics committee

**Under which criteria data/document could be used**

Ethical evaluation and review articles without financial conflicts of interest.

**From where data/document is obtainable**

Responsible Researcher Dr farhadnajmeddin by the following email f-najmeddin@tums.ac.ir

**What processes are involved for a request to access data/document**

Data will be available within 2 weeks after the email check. The email should include the Conflict of interest disclosure

**Comments**