Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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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

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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
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Sponsors / Funding sources

1

Sponsor
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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
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Position
Assistant Professor
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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
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