Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Jun 2026

Comparison of the effect of preoperative administration of gabapentin and pregabalin on pain control after percutaneous nephrolithotomy

Protocol summary

Study aim
Determining the effect of pain control from gabapentin and pregabalin after Percutaneous nephrolithotomy

Design
Clinical trial with control group, with parallel groups, single-blind, randomized, phase 2, on 66 patients. A random number table will be used for randomization.

Settings and conduct
The aim of this study was to determine the effect of pain control from gabapentin and pregabalin after Percutaneous nephrolithotomy. This study is a single blind, randomized clinical trial. The study population is patients undergoing Percutaneous nephrolithotomy. Patients will receive randomly pregabalin capsules 150 mg, gabapentin capsules 300 mg and placebo capsules in 3 intervention groups. The patient will be unaware of the group assigned to him.

Participants/Inclusion and exclusion criteria
Inclusion criteria for participants: Patients undergoing percutaneous nephrolithotomy surgery, ASA class I, II, age between 20-60 years, patient informed consent. Exclusion criteria for participants: age under 20 years and over 60 years, history of preoperative renal dysfunction, history of cardiovascular or lung diseases.

Intervention groups
Intervention group 1: Patients will receive a 150 mg pregabalin capsule two hours before surgery. Intervention group 2: Patients will receive gabapentin 300 mg capsule two hours before surgery. Control group: Patients will receive placebo capsules two hours before surgery.

Main outcome variables
The main outcome of the study: pain.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200802048275N1**
Registration date: **2021-01-06, 1399/10/17**
Registration timing: **prospective**

Last update: **2021-01-06, 1399/10/17**
Update count: **0**

Registration date
2021-01-06, 1399/10/17

Registrant information

Name
Leila Seyedtabaii

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 7742 0933

Email address
leiladrml@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-01-20, 1399/11/01

Expected recruitment end date
2021-02-19, 1399/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of preoperative administration of gabapentin and pregabalin on pain control after percutaneous nephrolithotomy

Public title

Effect of gabapentin and pregabalin on pain control after percutaneous nephrolithotomy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patient undergoing percutaneous nephrolithotomy Class ASA I, II Age between 20-60 years Patient informed consent

Exclusion criteria:
Age under 20 years and over 60 years History of preoperative renal dysfunction History of cardiovascular or lung disease

Age
From **20 years** old to **60 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients receive a random number using the random number table according to their priority entry to the center that matches the numbers on the sealed envelopes. Inside the sealed envelopes is one of the codes A, B and C. A represents the first intervention group that will receive 20 ml of sterile normal saline, B represents the second intervention group that will receive 40 ml of sterile normal saline, and C represents the third intervention group that will receive 60 ml of normal sterile saline. The number of patient in each group is equal.

Blinding (investigator's opinion)
Double blinded

Blinding description
Study participants are not aware of their assigned group and will be unaware of the drug used. Of course, they participate in the study with informed consent.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Next to Milad Tower, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
1449614535

Approval date
2020-07-19, 1399/04/29

Ethics committee reference number
IR.IUMS.FMD.REC.1399.277

Health conditions studied

1

Description of health condition studied
Percutaneous nephrolithotomy

ICD-10 code
N20.0

ICD-10 code description
Calculus of kidney

Primary outcomes

1

Description
Pain

Timepoint
Before surgery, recovery, 4, 6 and 12 hours after surgery

Method of measurement
Visual Analogue Scale (VAS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: wo hours before surgery, a 150 mg pregabalin capsule is given.

Category
Treatment - Drugs

2

Description
Intervention group: two hours before surgery, a 300 mg gabapentin capsule is given.

Category
Treatment - Drugs

3

Description

Control group: two hours before surgery, a placebo capsule is given.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hasheminejad Hospital

Full name of responsible person

Masoud Ghorbanloo

Street address

Shahid Valinejad Alley, Above Vanak Square, Vali Asr St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Masoud Ghorbanloo

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Medical doctor

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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
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available

Title and more details about the data/document
All potential data is shared after unidentifiable people.

When the data will become available and for how long
Start of access period 6 months after printing results

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
There are no special conditions.

From where data/document is obtainable
Dr. Massoud Ghorbanloo

What processes are involved for a request to access data/document
After reviewing the applicant's request, it will be sent to him.

Comments