Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

The effect of preoperative administration of pregabalin on anxiety and pain in patients after PCNL

Protocol summary

Study aim
The aim of this study was to provide an appropriate pharmacological solution to reduce patients 'anxiety before PCNL surgery and also to reduce patients' pain after PCNL surgery.

Design
A clinical trial with the control group, with parallel groups, double-blind, randomly sealed by envelope method, total sample size of 100 patients, phase 3 trial

Settings and conduct
This study will be performed in Shohada Tajrish Hospital in Tehran. Patients who are candidates for PCNL surgery due to kidney stones are randomly divided into 4 groups and will receive 75 mg pregabalin, 150 mg pregabalin, 300 mg pregabalin, and placebo, respectively, 2 hours before surgery. For all patients, the level of anxiety will be measured and compared using the Hamilton Questionnaire (HAM-A) before and 1.5 hours after medication. After surgery, patients' pain will be measured and compared based on the VAS questionnaire, at 2, 6, 12, and 24 hours after surgery. It is two-way blind and the questioner and the patient will not know how to divide patients into the mentioned groups.

Participants/Inclusion and exclusion criteria
Participants in this study are patients who are candidates for PCNL surgery due to kidney stones. Inclusion criteria include: 18 to 60 years old and ASA score one or two. Exclusion criteria include taking drugs that interact with pregabalin, including (rosiglitazone - pioglitazone - benzodiazepines - ACEIs) ؛ people who use alcohol؛ a history of psychiatric disorders including suicidal ideation and depression؛ history of heart failure Has؛ history of kidney failure and pregnant or lactating women.

Intervention groups
Patients are divided into 4 groups. 2 hours before surgery, the first group will receive 75 mg pregabalin, the second group 150 mg pregabalin, the third group 300 mg pregabalin, and the fourth group placebo.

Main outcome variables
Reduce pre-operative anxiety; Reduce postoperative pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200402046915N2**
Registration date: **2022-02-19, 1400/11/30**
Registration timing: **prospective**

Last update: **2022-02-19, 1400/11/30**
Update count: **0**

Registration date
2022-02-19, 1400/11/30

Registrant information

Name
Seyyed Ali Hojjati

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2282 9356

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-04-03, 1401/01/14

Expected recruitment end date
2022-07-05, 1401/04/14

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preoperative administration of pregabalin on anxiety and pain in patients after PCNL

Public title

The effect of pregabalin on pain and anxiety in patients undergoing PCNL surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years The patient undergoes PCNL surgery ASA class 1 or 2

Exclusion criteria:

Use of drugs that interact with pregabalin, including: (rosiglitazone - pioglitazone - benzodiazepines - ACEIs) People who drink alcohol History of psychiatric disorders including suicidal ideation and depression History of Heart Failure History of Renal Failure Pregnant or lactating women

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients randomly choose a number between 1 and 100 based on the priority of entering the medical center and hospitalization. Then they open the sealed envelope they want to match the selected number. The envelopes contain the letters A, B, C and D, according to which patients are randomly divided into 4 groups.

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 Shahid Beheshti University of Medical Sciences

Street address

Shohada Tajrish Hospital, Shahrdari Street, Tajrish Square

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2022-01-09, 1400/10/19

Ethics committee reference number

IR.SBMU.RETECH.REC.1400.762

Health conditions studied

1

Description of health condition studied

Calculus of kidney

ICD-10 code

N20.0

ICD-10 code description

Calculus of kidney

Primary outcomes

1

Description

Postoperative pain

Timepoint

2, 6, 12 and 24 hours after surgery

Method of measurement

VAS questionnaire

2

Description

Anxiety before surgery

Timepoint

2 hours before surgery and 0.5 hours before surgery

Method of measurement

Hamilton (HAM-A) questionnaire

Secondary outcomes

1

Description

Side effects of pregabalin

Timepoint

After the surgery

Method of measurement
A checklist of pregabalin side effects will be prepared and the patient will be asked after surgery.

Intervention groups

1

Description
Intervention group: Patients receiving pregabalin
Category
Prevention

2

Description
Control group: Patients receiving placebo
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohada Tajrish hospital
Full name of responsible person
Seyyed Ali Hojjati
Street address
Shohada Tajrish Hospital, Shahrdari Street, Tajrish Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Shahid Beheshti Medical University, Near the Taleghani Hospital, Yaman Street, Shahid Chamran Highway
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1985717443
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info@sbmu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyyed Ali Hojjati
Position
Resident
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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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
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Only part of the data, such as information about the main outcome can be shared.
When the data will become available and for how long
Start of access period 6 months after publishing the results.
To whom data/document is available
Our data will only be available to researchers working in the academic centers.
Under which criteria data/document could be used
Possible analyzes are performed in SPSS software.
From where data/document is obtainable
Applicants should email the following e-mail address to receive the documents: sah.hojjati@sbmu.ac.ir
What processes are involved for a request to access data/document
The applicant can submit his / her request and receive the documents 6 months after the publication of the results via the following e-mail: sah.hojjati@sbmu.ac.ir
Comments