

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 21 2282 9356

Email address

sah.hojjati@sbmu.ac.ir

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, Shahr-dari 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, Shahr-dari Street, Tajrish Square

City

Tehran

Province

Tehran

Postal code

1989934148

Phone

+98 21 2271 8001

Email

sah.hojjati@sbmu.ac.ir

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

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 23871

Email

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

Medical doctor

Other areas of specialty/work

Urology

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Person responsible for scientific inquiries

Contact

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Seyyed Ali Hojjati

Position

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Latest degree

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