

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Evaluation the effect of Gabapentin on the pain after inguinal hernia repair surgery in general anesthesia

Protocol summary

Study aim

The main purpose of this study was to determine the effect of gabapentin on pain after inguinal hernia repair surgery in general anesthesia.

Design

A concealed, randomized, blinded, =controlled clinical trial with a parallel group design of 60 patients. Computerized block randomization program (STATA14 software) will be used for randomization.

Settings and conduct

The aim of this study was to evaluate the effect of gabapentin on pain after inguinal hernia repair surgery on 60 patients indicated for surgery under general anesthesia in Khatam Al-Anbia Hospital in Shahrud in 2020. Patients were randomly assigned to the intervention group (who will receive gabapentin capsules one hour before surgery) and the control group (who will receive a placebo capsule similar in shape and size to gabapentin capsules containing starch powder). It should be noted that the patient and the researcher recording the information will not know the type of drug received.

Participants/Inclusion and exclusion criteria

Patients with indirect inguinal hernia who have indication for repair surgery under general anesthesia and consent to enter the study. Patients with coagulation disorders and hypersensitivity to gabapentin will not be included in the study.

Intervention groups

The intervention group will receive gabapentin capsules (Caspian Drug Company of Rasht) at a dose of 400 mg orally one hour before surgery. The control group will receive the same capsule, which has been replaced with starch powder, one hour before the surgery.

Main outcome variables

Pain after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190219042753N1**

Registration date: **2020-08-21, 1399/05/31**

Registration timing: **prospective**

Last update: **2020-08-21, 1399/05/31**

Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Farzaneh Rahchamani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 4566 3213

Email address

farzaneh.rah.chamani.2020@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-08-31, 1399/06/10

Expected recruitment end date

2020-11-20, 1399/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of Gabapentin on the pain after inguinal hernia repair surgery in general anesthesia

Public title

The effect of Gabapentin on the pain after inguinal hernia repair surgery

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Unilateral indirect inguinal hernia
Consent to enter the study
Indication of hernia repair surgery under general anesthesia

Exclusion criteria:

Coagulation disorders
Psychological and memory disorders
Height less than 145 cm
Weight more than 100 kg
History of alcohol or drug abuse
History of taking antacid drugs containing aluminum and magnesium
Known allergy to gabapentin

Age

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

Gender

Male

Phase

2-3

Groups that have been masked

- Participant
- Care provider

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The computerized block randomization (block sizes of 4 and 6) will be carried out in this study. An independent clinical epidemiologist, who will not be involved in the conduct of the study used a computerized block randomization program (STATA14 software) to produce the allocation codes. The randomization sequences will be concealed in lightproof, sealed envelopes. The research assistant opened sealed, numbered, opaque envelopes containing allocation codes. The eligible participants will be randomized to two equal groups (gabapentin or placebo) according to the randomization list after signing informed consent form

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will not be aware of the type of medication they receive and the second executor of the research project will complete the questionnaire at the end of the treatment without knowledge of the two groups. Also the data will be analyzed without any information about group selection

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Islamic Azad University of Shahrood

Street address

No.1, Jirudi Ave., Sani Blvd., Narmak

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shahrood

Province

Semnan

Postal code

1646764863

Approval date

2018-01-02, 1396/10/12

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1397.023

Health conditions studied**1****Description of health condition studied**

Indirect inguinal hernia

ICD-10 code

K40.90

ICD-10 code description

Unilateral inguinal hernia, without obstruction or gangrene, not specified as recurrent

Primary outcomes**1****Description**

Pain after surgery

Timepoint

One and eight hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes**1****Description**

Complications of anesthesia include nausea and vomiting

Timepoint

One and eight hours after surgery

Method of measurement

Asking from patient and recording in the checklist

2**Description**

Duration of hospitalization

Timepoint

At the time of discharging

Method of measurement

Checking the file and recording in the checklist

Intervention groups**1****Description**

Intervention group: Gabapentin capsules (Caspian Drug Company of Rasht) with a dose of 400 mg will be prescribed as a single dose one hour before surgery.

Category

Treatment - Drugs

2**Description**

Control group: The placebo capsule with the same shape and size as the gabapentin capsule containing starch powder will be prescribed one hour before surgery.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Khatam Al-Anbiya Hospital in Shahrood

Full name of responsible person

Seyedeh Fatemeh Amir Khalili

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No.45 , First Alley, Mofateh St , Station St

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Sahebali Monafi

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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

Islamic Azad University

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**

Islamic Azad University

Full name of responsible person

Farzaneh Rahchamani

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be 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