Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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 Shahroud 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 carried out in this study. An independent clinical epidemiologist, who will not involved in the conduct of the study used a computerized block randomization program (STATA14 software) uses 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
City
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
Street address
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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shahrood.azad.university@gmail.com
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
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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