Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of pain levels after abdominal surgery in patients receiving pregabalin and famotidine with pregabalin and diphenhydramine in the hospitals of Islamic Azad University, Tehran Medical Branch in 2022

Protocol summary

Study aim

Determining the amount of pain after abdominal surgery in patients receiving pregabalin and famotidine with pregabalin and diphenhydramine

Design

A double-blind, parallel-group, randomized clinical trial on 34 patients. Randomized by online random number table

Settings and conduct

In order to make this study double-blind, the drugs used for the patients at the beginning of the study were divided into A/B groups by the head of the surgery department so that the researcher and the participants did not know the type of drug received. Medications were prescribed two hours before surgery, along with 50 cc water according to the following instruction: Weight less or equal to 60 kg a tablespoon of diphen hydramin syrup. More weight or than 60 kg two tablespoons of diphen hydramin syrup. Famotidine 75 mg with 50 cc of water. At the time of entering the recovery room and at 6, 12, 24 hours after the operation, the pain level of the patients was measured based on the VAS scale, and if the VAS was >5, 30-50 mg of pethidine was injected intravenously. At the end of the first day, the amount of narcotics used was recorded in the questionnaire by a trained nurse.

Participants/Inclusion and exclusion criteria

Age 15-75 years old; informed and written consent; ASA 1 and 2; no use of drugs and alcohol; elective surgery

Intervention groups

Group A (receiver of pregabalin and famotidine) and B (receiver of pregabalin and diphenhydramine)

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230106057067N1**
Registration date: **2023-03-19, 1401/12/28**
Registration timing: **retrospective**

Last update: **2023-03-19, 1401/12/28**
Update count: **0**

Registration date

2023-03-19, 1401/12/28

Registrant information

Name

parnian motamed chaboki

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8827 9693

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

2022-06-22, 1401/04/01

Actual recruitment end date

2022-12-22, 1401/10/01

Trial completion date

2022-12-22, 1401/10/01

Scientific title
Comparison of pain levels after abdominal surgery in patients receiving pregabalin and famotidine with pregabalin and diphenhydramine in the hospitals of Islamic Azad University, Tehran Medical Branch in 2022

Public title
Comparison of pain levels after abdominal surgery in patients receiving pregabalin and famotidine with pregabalin and diphenhydramine

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age 15-75 years old Informed and written consent ASA class 1 or 2 No abuse of drugs and alcohol Elective surgery

Exclusion criteria:
Loss of consciousness Hemodynamic disorder Abnormal intraoperative bleeding Operation is more than 4 hours

Age
From **15 years** old to **75 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size
Target sample size: **34**
Actual sample size reached: **34**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, first, a list of all patients who were willing to participate in the research was prepared, and after matching the patients who met the inclusion criteria, we assigned a number to each patient. We considered numbers 1 to 17 as group A and 18 to 34 as group B. Then, using an online random number table, the patients were placed in two groups (A group receiving pregabalin and famotidine and B group receiving pregabalin and diphenhydramine).

Blinding (investigator's opinion)
Double blinded

Blinding description
Due to the double-blindness of this study, the drugs used for the patients were divided in A/B form by the head of the surgery department at the beginning of the study so that the researcher and the participants did not know the type of drug received.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address
Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

City
Tehran

Province
Tehran

Postal code
1949635881

Approval date
2022-06-15, 1401/03/25

Ethics committee reference number
IR.IAU.TMU.REC.1401.071

Health conditions studied

1

Description of health condition studied
Abdominal surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
PAIN

Timepoint
After entering recovery and 24, 12, 6 hours after the operation

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
One group received pregabalin and famotidine. The way to calculate the amount of drug and puff spray in patients was as follows: Famotidine 40 mg. Pregabalin 75 mg

Category
Treatment - Drugs

2

Description
One group received pregabalin and diphenhydramine. The way to calculate the amount of medicine and puff spray in patients was as follows: weight less than or equal to 60 kg, one spoon of diphenhydramine syrup. Weight more than 60 kg, two spoons of diphenhydramine syrup. Pregabalin 75 mg
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Hospitals affiliated to Tehran Islamic Azad University of Medical Sciences (Boali, Amir and Farhikht
Full name of responsible person
Mahnaz Narimani Zamanabadi
Street address
Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Dr. Majid Naqipour
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Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran
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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
Private
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
Parnian Motamed Chabaki
Position
Associate professor
Latest degree
Medical doctor
Other areas of specialty/work
General Practitioner
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Person responsible for scientific inquiries

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Latest degree

Subspecialist

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Anesthesiology

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Person responsible for updating data

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Other areas of specialty/work
Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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