

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jun 2026

Comparative study of the efficacy of acetaminophen and gabapentin used preoperatively on postoperative anorectal pain

Protocol summary

Study aim

1. Determination of pain after anorectal surgery in acetaminophen group 2. Determination of pain after anorectal surgery in gabapentin group 3. Determination of pain after anorectal surgery in placebo group 4. Comparison of the efficacy of acetaminophen and gabapentin before surgery on pain after anorectal surgery 5. Determining and comparing the amount of analgesic received in three treatment groups

Design

A clinical trial with three intervention groups with factorial groups, double-blind, randomized, was performed on 144 patients, each group of 48 people. Block randomization is used for randomization.

Settings and conduct

Eligible patients are divided into three groups after obtaining informed consent using block randomization. Acetaminophen, gabapentin and placebo groups. Patients received a dose of the drug two hours before surgery and two hours after surgery. The amount of postoperative pain was measured in three groups and compared with each other. The study is performed in Shahid Beheshti Hospital in Qom in a double-blind manner. Intervention and researcher groups are blind

Participants/Inclusion and exclusion criteria

Not addict people who are candidates for colorectal surgery and have no other underlying disease enter the study with informed consent and are excluded from the study in case of drug side effects.

Intervention groups

There are three intervention groups including the group receiving oral acetaminophen 500, oral gabapentin 300 and the placebo group in this study. The acetaminophen and gabapentin groups receive the same dose two hours before surgery, and the effect of these two drugs on postoperative pain control is compared with the placebo group and also with each other.

Main outcome variables

By comparing the efficacy of acetaminophen with

gabapentin preoperatively on postoperative anorectal pain compared with placebo, postoperative pain in patients can be reduced.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120118008769N4**

Registration date: **2021-10-19, 1400/07/27**

Registration timing: **retrospective**

Last update: **2021-10-19, 1400/07/27**

Update count: **0**

Registration date

2021-10-19, 1400/07/27

Registrant information

Name

Seyed Jalal Eshagh Hosseini

Name of organization / entity

Qom University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 25171181

Email address

j.hosseini@muq.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-07, 1397/10/17

Expected recruitment end date

2020-09-08, 1399/06/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the efficacy of acetaminophen and gabapentin used preoperatively on postoperative anorectal pain

Public title

The effect of gabapentin and acetaminophen on postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Anorectal disease Satisfaction with participation in the study Lack of other painful diseases

Exclusion criteria:

Improper use of the drug Creating drug side effects Patient dissatisfaction Addicted people

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

- Participant

Sample size

Target sample size: **14**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, the patient and the lead researcher give the drug to the patient before surgery and record the pain score. Do not know the type of drug used.

Placebo

Used

Assignment

Factorial

Other design features**Secondary Ids**

empty

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

Ethics Committee of Qom University of Medical Sciences

Street address

Qom University of Medical Science, Shahid Lavasani St

City

Qom

Province

Ghous

Postal code

3713649373

Approval date

2020-08-25, 1399/06/04

Ethics committee reference number

IR.MUQ.REC.1400.011

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

Comparative study of the efficacy of acetaminophen and gabapentin used pre operative on pain after anorectal surgery

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

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

Amount of pain (pain score)

Timepoint

One hour after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

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

Intervention group 1: group receiving oral tablets acetaminophen 500 mg from Galenus company one preoperative dose

Category

Treatment - Drugs

2**Description**

Intervention group 2: Group receiving oral tablets gabapentin 300 mg from Razak company one dose before surgery

Category

Treatment - Drugs

3

Description

Control group: placebo group that does not receive any preoperative medication.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Seyed Jalal Eshaq Hoseini

Street address

Shahid Beheshti St

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Shahidbeheshti@muq.ac.ir

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

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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

Ghous University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Private

Domestic or foreign origin

Foreign

Category of foreign source of funding

Sponsor: country of origin

Country of origin

IR

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Ghous University of Medical Sciences

Full name of responsible person

Seyed Jalal eshaq Hoseini

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

General Surgery

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Person responsible for updating data

Contact

Name of organization / entity
Ghoum University of Medical Sciences
Full name of responsible person
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Position
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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