Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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

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Iran (Islamic Republic of)

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+98 25171181

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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
Ghoum
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 tabletes 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 Eshaqh Hoseini
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Shahid Beheshti St
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ghoum University of Medical Sciences
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deanoduniversity@muq.ac.ir
Web page address
http://www.muq.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ghoum 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
Ghoum University of Medical Sciences
Full name of responsible person
Seyed Jalal eshaqh 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

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Full name of responsible person

Amin seifadini

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

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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