

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effect of acetazolamide and paracetamol on referral pains following laparoscopic cholecystectomy

Protocol summary

Study aim

Comparison of acetazolamide and paracetamol on postoperative referral pain in patients undergoing laparoscopic cholecystectomy

Design

A double-blinded, parallel-group clinical trial with random sampling and allocation in 2 groups of intervention and 1 group control .

Settings and conduct

A recent study was conducted on 114 patients undergoing laparoscopic cholecystectomy and based on their purpose. The patients were divided into 3 groups: acetazolamide, paracetamol and placebo.

Participants/Inclusion and exclusion criteria

Inclusion: All patients undergoing laparoscopic cholecystectomy Exclusion: 1. Patients with an underlying disease with impaired sense of pain . Exit of natural pathology including bleeding from the cystic artery or expelling bile into the peritoneum. The incidence of any complications associated with surgery, including duct injury, bile ducts, even if detected after discharge and during the fallopian occlusion. Receive analgesic and analgesic drugs within 24 and 48 hours, 5. Drug addict, 6. Contraindications of acetaminophen, acetazolamide, lactose and starch, 7. The presence of inflammation based on the surgeon's observations during surgery, in which the adhesions and dyslexia are over-regulated 8. Patients in need of drainage

Intervention groups

1. acetazolamide group: received acetazolamide before induction of anesthesia + administration of placebo paracetamol 2. paracetamol group: 1 gram paracetamol administration at the end of surgery for slow infusion over 15 minutes plus 100 cc of crystalloid solution + placebo before induction of anesthesia 3. placebo group: Placebo : acetazolamide)before induction of anesthesia + administration of placebo at the end of surgery.

Main outcome variables

Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180603039958N1**

Registration date: **2019-01-24, 1397/11/04**

Registration timing: **retrospective**

Last update: **2019-01-24, 1397/11/04**

Update count: **0**

Registration date

2019-01-24, 1397/11/04

Registrant information

Name

Arash Peyvandi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3852 1121

Email address

nrc@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2009-03-21, 1388/01/01

Expected recruitment end date

2009-09-23, 1388/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of acetazolamide and paracetamol on referral pains following laparoscopic cholecystectomy

Public title

Effect of acetazolamide and paracetamol on referral pain after surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients undergoing laparoscopic cholecystectomy

Exclusion criteria:

Having a disease that causes pain in the sensation
Receiving analgesic and anti-inflammatory drugs within 48-48 hours
Drug addicts
Contraindications for acetaminophen, acetazolamide, lactose and starch (used in placebo)
The presence of inflammation based on surgical surgeries in a way that overlaps adhesions and dyslexia is more likely to last longer than an hour.
Patients Needed Dren

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be assigned to the control or intervention group by drawing a random number out of a bag.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants will not be informed about which group they are in. Also, the data analyst will be blind to which group the participants are assigned

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Ibn sina street Imam Reza Square, Imam Reza Hospital

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913316

Approval date

2011-10-15, 1390/07/23

Ethics committee reference number

IR.MUMS.REC.1390.14

Health conditions studied

1

Description of health condition studied

referred postoperative pain after laparoscopic cholecystectomy

ICD-10 code

Z90.410

ICD-10 code description

Acquired total absence of pancreas

Primary outcomes

1

Description

Pain in cholecystectomy surgery by laparoscopy due to uncomplicated

Timepoint

Immediately before surgery, after surgery and after awakening, discharge from the recovery, the day after surgery, and upon discharge from the hospital

Method of measurement

Questionnaire based on purpose and patient view

Secondary outcomes

empty

Intervention groups

1

Description

The first group (acetazolamide group) received acetazolamide tablets 250 mg half an hour before induction of anesthesia plus 20 cc water + placebo administration Paracetamol (isotonic saline solution) at the end of the surgery half an hour

Category

Treatment - Drugs

2

Description

Control group: Administration of 1gr of paracetamol at the end of the surgical operation as a slow infusion over 15 minutes plus 100 cc of crystalloid solution + receiving placebo (acetazolamide) half an hour before induction of anesthesia with 20cc of water

Category

Treatment - Drugs

3

Description

Intervention group2: 1 gram paracetamol administered at the end of surgery for slow infusion in 15 minutes, plus 100 cc of crystalloid solution + placebo (acetazolamide) 0.5 hour before induction of anesthesia with 20cc water

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Cancer Surgery Research Center

Full name of responsible person

Mahsa Rajaei

Street address

Iman Reza Square, Imam Reza Hospital, Ave.

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+98 51 3802 2677

Email

nrc@mums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

Street address

International Office Administration Center (Qoreishi Building) ; Daneshgah St.

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ramresearch@mums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Mashhad University of Medical Sciences

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

Mashhad University of Medical Sciences

Full name of responsible person

Mahsa Rajaei

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Specialist
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only part of the questionnaire information is available

When the data will become available and for how long

After publishing the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

The use of drugs to estimate pain relief after surgery

From where data/document is obtainable

Available in Google & Pubmed

What processes are involved for a request to access data/document

Immediately after publishing in journal

Comments