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 Mashahd 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 painafter 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 Rajaee
Street address
Iman Reza Square, Imam Reza Hospital, Ave.
City
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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 Offic Administration Center (Qoreishi Building) ; Daneshgah St.
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913
Phone
+98 51 3802 2677
Email
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 Rajaee
Position
Specialist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Iman Reza Square, Imam Reza Hospital, Ave.
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Person responsible for scientific inquiries

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Person responsible for updating data

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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