Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of the effect of acetazolamide and paracetamol on referred postoperative pain after laparoscopic cholecystectomy

Protocol summary

Summary

Patients undergoing laparoscopic cholecystectomy experience sever referred pain postoperatively. They usually require more analgesic consumption and long-term hospital stay, which consequently result in higher costs. Thus, this study is aimed to investigate the effect of acetazolamide and paracetamol on referred pain of candidate patients for laparoscopic cholecystectomy, and to find a cost-effective way to reduce pain. In a randomized, controlled, double blinded trial, 114 adult patients with uncomplicated cholelithiasis undergoing laparoscopic cholecystectomy will be evaluated with regard to postoperative referred pain. Patients are randomly assigned to 3 groups to receive 250 mg acetazolamide, 1 gr paracetamol or placebo. In case of any complications, such as ductal damage, bile leakage, biliary ascites or excessive bleeding during surgery, or if the surgeon has to insert a drain at the end of operation, then those patients are excluded from study. The postoperative pain will be assessed according to the location, intensity and type of pain, immediately before and after surgery, after return of consciousness, at the time of stay in post-operative care unit, during 24 hours stay in the ward and at the time of discharge. Also, the patients' demographic data such as age and gender, the dose and kind of analgesic will be documented.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206108384N2**
Registration date: **2012-06-25, 1391/04/05**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2012-06-25, 1391/04/05

Registrant information

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Recruitment status

Recruitment complete

Funding source

Mashhad University of Medical Sciences

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2013-05-21, 1392/02/31

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 referred postoperative pain after laparoscopic cholecystectomy

Public title

Comparison of the effect of acetazolamide and paracetamol on referred postoperative pain after laparoscopic gallbladder surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria 1- Patients candidates for laparoscopic cholecystectomy Excusion Criteria 1- Patients with pain disorder 2- Intraoperative complications such as cystic artery bleeding, leakage of bile into the peritoneal cavity 3- Postoperative complications such as bile duct injury, bile leakage, or biliary ascites. 4- Consumption of any narcotics and analgesics within 1 or 2 days before surgery. 5- Narcotics addicts 6- Contraindications to acetaminophen and acetasolamide, also lactose and starch (as components of the placebo) 7- Presence of inflammation, adhesions and excessive dissection which may prolong the operative time for more than 1 hours 8- The need for drain insertion

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **114**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Mashhad University of Medical Sciences

Street address
Ghoreyshi Building, Daneshgah Street

City
Mashhad

Postal code

Approval date
2011-10-15, 1390/07/23

Ethics committee reference number
900337

Health conditions studied

1

Description of health condition studied
Cholecystitis

ICD-10 code
K81

ICD-10 code description
Cholecystitis

Primary outcomes

1

Description
Pain intensity

Timepoint
Immediately before and after surgery, after return of consciousness, at the time of stay in post-operative care unit, during 24 hours stay in the ward and at the time of discharge.

Method of measurement
Visual Analog Scale (VAS)

2

Description
Pain location

Timepoint
Immediately before and after surgery, after return of consciousness, at the time of stay in post-operative care unit, during 24 hours stay in the ward and at the time of discharge.

Method of measurement
Objectively

Secondary outcomes

1

Description
Analgesic consumption

Timepoint
Immediately before and/or after surgery and/or after return of consciousness and/or at the time of stay in post-operative care unit and/or during 24 hours stay in the ward and/or at the time of discharge

Method of measurement
mg

Intervention groups

1

Description
Acetazolamide tablet before induction of anesthesia & placebo of paracetamol at the end of surgery

Category
Treatment - Drugs

2

Description
Placebo tablet of acetazolamide before induction of anesthesia & Placebo Paracetamol at the end of surgery

Category

Treatment - Drugs

3

Description
Paracetamol infusion at the end of surgery & placebo tablet of acetazolamide before induction of anesthesia
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Surgical Oncology Research Center
Full name of responsible person
Dr. Arash Peivandi Yazdi
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Surgical Oncology Research Center, Imam Reza Hospital, Faculty of Medicine, Mashhad University of Medical Sciences
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Dr. Mohsen Tafaghodi
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Vice chancellor for Research, Ghoreyshi Building, Daneshgah Street
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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
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty