

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

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

Protocol summary

2012-06-25, 1391/04/05

Summary

Patients undergoing laparoscopic cholecystectomy experience severe 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.

Registrant information

Name

Arash Peivandi Yazdi

Name of organization / entity

Mashhad University of Medical Sciences

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Iran (Islamic Republic of)

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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

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

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
Excision 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 acetazolamide, 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

Street address

Surgical Oncology Research Center, Imam Reza Hospital, Faculty of Medicine, Mashhad University of Medical Sciences

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Mohsen Tafaghodi

Street address

Vice chancellor for Research, Ghoreyshi Building, Daneshgah Street

City

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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

Contact

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

Dr. Arash Peivandi Yazdi

Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

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Contact

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Full name of responsible person

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Position

Assistant Professor of Anesthesiology

Other areas of specialty/work

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Assistant Professor of Anesthesiology

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Web page address

<http://www.mums.ac.ir/sorc>

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