Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Effect of Pre-Operative Administration of Acetazolamide on Post-Operational Shoulder Referred Pain and Abdominal Pain in Laparoscopic Cholecystectomy Candidates: a Randomized Placebo-Controlled Clinical Trial

Protocol summary

Summary

The aim of this study is to compare the efficacy of pre-operative acetazolamide in relieving post-operational pain after laparoscopy. The present study is a randomized, double-blinded phase II clinical trial, with a parallel structure, that will be carried out in Alzahra Hospital during October 2017. 111 cholecystectomy patients that are qualified for this operation will participate in the present study. Since we want to evaluate the effect of acetazolamide dosage, subjects will be randomized into 0 (placebo), 5 and 10 mg/kg receiving groups through blocking and stratification methods. The drug in these groups is administered 1 hour before the laparoscopy operation in the form of tablet (acetazolamide or placebo). Afterwards, patients will be closely followed and Visual Analog Scale score and Modified Aldrete score will be assessed in them to estimate their pain and blood oxygen levels respectively, at certain times from the time of operation until the time of discharge. Therefore, primary outcomes include: VAS score; and MAS score. Secondary outcomes include: time before requesting opioid, amount of opioid (opioid dose) used to deteriorate pain, distribution of pain locations and time before discharge from hospital.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081935778N1**
Registration date: **2017-10-29, 1396/08/07**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-29, 1396/08/07

Registrant information

Name

Kiarash Salimi

Name of organization / entity

Isfahan University of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Isfahan University of Medical Sciences

Expected recruitment start date

2017-09-29, 1396/07/07

Expected recruitment end date

2017-10-10, 1396/07/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Pre-Operative Administration of Acetazolamide on Post-Operational Shoulder Referred Pain and Abdominal Pain in Laparoscopic Cholecystectomy Candidates: a Randomized Placebo-Controlled Clinical Trial

Public title
Pre-Operative Acetazolamide Administration for Post-Operative Abdominal Pain Releif
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria: Subjects must be candidates for laparoscopic cholecystectomy (ages 18 to 65) Exclusion criteria: Subject with a history of any hematologic disorders; chronic metabolic acidosis; chronic obstructive pulmonary disease; kidney transplantation; allergy to sufonamides; patients with present history of electrolyte disturbances; CNS dysfunction; renal failure or creatinine level higher than 2mg/dl; pregnancy; any liver diseases; or patients with ongoing diuretic treatment.
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **111**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features
Subjects will be randomized using bolcking and stratification methods.

Secondary Ids

1

Registry name
None
Secondary trial Id
None
Registration date
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Committee of Ethics in Biomedical Research of Isfahan Uiversity of Medical Sciences
Street address
Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan
City
Isfahan
Postal code
Approval date
2017-01-03, 1395/10/14
Ethics committee reference number
ir.mui.rec.1395.3.142

Health conditions studied

1

Description of health condition studied
cholecystitis
ICD-10 code
K81
ICD-10 code description
Cholecystitis

Primary outcomes

1

Description
Abdominal Pain
Timepoint
first, second, and third 30 minutes within the operation, and first,second, and third 30 minutes within recovery, also at the time of discharge
Method of measurement
VAS questionnaire

2

Description
Modified Aldrete Score
Timepoint
first, second, and third 30 minutes within the operation, and first,second, and third 30 minutes within recovery, also at the time of discharge
Method of measurement
Physical examination for scoring; and pulse oxymetry

Secondary outcomes

1

Description
Time before requesting opioid
Timepoint
first, second, and third 30 minutes within the operation, and first,second, and third 30 minutes within recovery, also at the time of discharge
Method of measurement
Timer

2

Description
Amount of opioid used to deteriorate pain
Timepoint
first, second, and third 30 minutes within the operation,

and first,second, and third 30 minutes within recovery, also at the time of discharge

Method of measurement

Report by resident

3

Description

Distribution of pain location

Timepoint

first, second, and third 30 minutes within the operation, and first,second, and third 30 minutes within recovery, also at the time of discharge

Method of measurement

Physical Examination

4

Description

Time before discharge from hospital

Timepoint

first, second, and third 30 minutes within the operation, and first,second, and third 30 minutes within recovery, also at the time of discharge

Method of measurement

Timer

Intervention groups

1

Description

Intervention group 1:In this group patients will receive 10mg/Kg of Acetazolamide. Since estimated mean weight of patients is 75 Kg, each patient will be administered 6 halved 250-mg tablets (total of 750mg) 1 hour before laparoscopy operation.

Category

Prevention

2

Description

Control group:A placebo with identical appearance will be provided for each patient in this group. All patients in this group will be administered 6 halved placebo tablets 1 hour before laparoscopy operation.

Category

Placebo

3

Description

Intervention group 2:In this group patients will receive 5mg/Kg of Acetazolamide. Since estimated mean weight of patients is 75 Kg, each patient will be administered 3 halved 250-mg tablets (total of 375mg) and 3 halved placebo tablets 1 hour before laparoscopoy operation.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Alzahra Hospital

Full name of responsible person

Payman Soleimani

Street address

Alzahra Hospital, Soffeh St., Isfahan

City

Isfahan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Isfahan University of Medical Sciences

Full name of responsible person

Dr Parvin Sajedi

Street address

Faculty of Medicine, Isfahan University of Medical Sciences, Hezar Jarib St., Isfahan

City

Isfahan

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice Chancellor for research of Isfahan 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

Isfahan University of Medical Sciences

Full name of responsible person

Payman Soleimani

Position

Medical Student

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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