

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jul 2026

Assessment of the prophylactic combined effect of diphenhydramine with paracetamol on agitation and pain after laparoscopic cholecystectomy

Protocol summary

Study aim

Determining the prophylactic effect of diphenhydramine with paracetamol on agitation and pain after laparoscopic cholecystectomy

Design

60 patients in the age group of 20 to 60 years with ASA class one and two will undergo laparoscopic cholecystectomy with selective general anesthesia.

Settings and conduct

Patients aged 20 to 60 years with ASA class one and two undergoing laparoscopic cholecystectomy with selective general anesthesia referred to Imam Khomeini Hospital in Urmia the night before surgery will receive 5 mg of diazepam oral drug. And on the day of operation will be randomly divided into two groups. In group (P), paracetamol will be injected simultaneously for more than 15 minutes (1 g of paracetamol per 100 ml of 0.9% NaCl) 10 minutes after induction of anesthesia. became. In the DP group, diphenhydramine 0.4 mg / kg intravenously in 100 ml of 0.9% NaCl with paracetamol will be injected together for 10 minutes after induction of anesthesia.

Participants/Inclusion and exclusion criteria

The age group of 20 to 60 years with ASA class one and two will undergo laparoscopic cholecystectomy with elective general anesthesia. Patients with hypertension, history of heart disease, gastritis, kidney and lung disease, stomach pain, mental health problems and drug addicts and people treated with beta-blockers, methyl dopa, monoamine oxidase inhibitors, analgesics, BMI Above 30 will be excluded from the study

Intervention groups

Intravenous paracetamol group and diphenhydramine group

Main outcome variables

Pain / agitation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170411033365N4**

Registration date: **2022-07-20, 1401/04/29**

Registration timing: **prospective**

Last update: **2022-07-20, 1401/04/29**

Update count: **0**

Registration date

2022-07-20, 1401/04/29

Registrant information

Name

Alireza Mahoori

Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

mahouri.a@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-22, 1401/05/31

Expected recruitment end date

2022-12-21, 1401/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Assessment of the prophylactic combined effect of diphenhydramine with paracetamol on agitation and pain after laparoscopic cholecystectomy

Public title

Assessment of the prophylactic combined effect of diphenhydramine with paracetamol on agitation and pain after laparoscopic cholecystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age group 20 to 60 years Patients with ASA class one and two undergo laparoscopic cholecystectomy Selective general anesthesia

Exclusion criteria:

Patients aged 20 to 60 years with ASA class one and two undergoing laparoscopic cholecystectomy

Age

From **20 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

The number of patients in this study will be 60 patients. Patients will be randomly divided into two equal groups by computer numbers via a certified true randomizer number generator (www.random.org, Android Play Store) and Based on the last number of the file number .From number of 0-30 in control group and 31-60 will be placed in Diphenhydramine and Paracetamol group. Target codes will be written and placed in sealed envelopes with sequential allocation using single blind method.

Blinding (investigator's opinion)

Single blinded

Blinding description

In this study, the clinical caregiver and outcome assessor will be unaware of which group each patient belongs to.

Placebo

Not used

Assignment

Parallel

Other design features

Determining the prophylactic effect of diphenhydramine with paracetamol on agitation and pain after laparoscopic cholecystectomy

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Urmia University of Medical Sciences

Street address

Imam Khomeini University Hospital-Ershad AVE-Modarres Blvd- Urmia-IRAN

City

Urmia

Province

West Azarbaijan

Postal code

5715789397

Approval date

2022-05-24, 1401/03/03

Ethics committee reference number

IR.UMSU.REC.1401.078

Health conditions studied

1

Description of health condition studied

Cholecystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Agitation and pain

Timepoint

In recovery and after transfer to the ward at 6, 12 and 24 hours after surgery

Method of measurement

The amount of visual scoring pain (VAS) from zero to 10 points and the amount of agitation at the time of recovery after 10, 20, 30 minutes after recovery, by four-point scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group (P), intravenous paracetamol will be injected simultaneously for more than 15 minutes (1 g of paracetamol per 100 ml of 0.9% NaCl) 10 minutes after induction of anesthesia.

Category

Treatment - Drugs

2

Description

Intervention group: In the DP group, diphenhydramine 0.4 mg / kg intravenously in 100 ml of 0.9% NaCl with paracetamol will be injected together for 10 minutes after induction of anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital in Urmia

Full name of responsible person

Dr. Alireza Mahouri

Street address

Imam Khomeini University Hospital-Ershad AVE-
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Saber Gholizadeh

Street address

Resalat Boulevard - Emergency Alley - Urmia
University of Medical Sciences

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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

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Alireza Mahouri

Position

Professor

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Alireza Mahouri

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available