

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

The effect of paracetamol, metoclopramide and combination of metoclopramide and paracetamol on pain severity after laparoscopic cholecystectomy and comparison with control group

Protocol summary

Study aim

Determining the effect of Paracetamol, Metoclopramide and combination of Metoclopramide and Paracetamol on pain severity after laparoscopic cholecystectomy and comparison with control group

Design

Clinical trial with control group, with parallel groups, randomized

Settings and conduct

The study was conducted in 1396-1397 in Al-Zahra Hospital , Isfahan. The target population are the patients who referred to Al-Zahra hospital for elective laparoscopic cholecystectomy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients aged 18-65 year referred to Al-Zahra hospital during the year 1396-1397 for elective laparoscopic cholecystectomy and classified as ASA physical status 1 or 2 were included Exclusion criteria: Pregnancy, Addiction to cigarette, opioid and alcohol, Weight over 100 kg, Chronic pain that lasts more than 6 months, Allergy to Metoclopramide or Acetaminophen, Anxiety before surgery, Taking any analgesic 24 hours before surgery

Intervention groups

In this clinical trial study, 100 patients undergoing laparoscopic cholecystectomy surgery referred to Alzahra Hospital in Isfahan were enrolled from 2015 to 2017. Patients were randomly divided into four groups receiving 15 mg/kg paracetamol or 0.15 mg/kg metoclopramide or 10 mg/kg paracetamol and 0.1 mg/kg metoclopramide or placebo. pain severity and hemodynamic variables were assessed in the groups.

Main outcome variables

Severity of pain! Hemodynamic variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190825044610N1**

Registration date: **2019-09-14, 1398/06/23**

Registration timing: **retrospective**

Last update: **2019-09-14, 1398/06/23**

Update count: **0**

Registration date

2019-09-14, 1398/06/23

Registrant information

Name

Seyyede Hosna Mirzajjani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3673 0416

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

2017-08-23, 1396/06/01

Actual recruitment end date

2018-12-03, 1397/09/12

Trial completion date

2018-12-03, 1397/09/12

Scientific title

The effect of paracetamol, metoclopramide and combination of metoclopramide and paracetamol on pain severity after laparoscopic cholecystectomy and comparison with control group

Public title

The effect of paracetamol and metoclopramide on postoperative pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients aged 18-65 year referred to Al-Zahra hospital during the year 1396-1397 for elective laparoscopic cholecystectomy and classified as ASA physical status 1 or 2 were included

Exclusion criteria:

Pregnancy Addiction to cigarette, opioid and alcohol Weight over 100 kg Chronic pain that lasts more than 6 months Allergy to metoclopramide or acetaminophen Anxiety before surgery Taking any analgesic 24 hours before surgery

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization method: Simple randomization
Randomization unit: Individual Randomization layer: Not done
Randomization tool: Random number table
How to create random sequence: Classification in groups like this:
Group A: 1-25 Group B: 26-50 Group C: 51-75 Group D: 76-100
Allocation concealment: Using numbered drug containers

Blinding (investigator's opinion)

Double blinded

Blinding description

A person who inject drugs is different from person who collect data

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Isfahan University of Medical Science

Street address

Isfahan University of Medical Science, Hezar Jarib Street, Isfahan, Iran

City

Isfahan

Province

Isfahan

Postal code

8174675731

Approval date

2018-01-17, 1396/10/27

Ethics committee reference number

IR.MUI.MED.REC.1397.120

Health conditions studied

1

Description of health condition studied

Postoperative pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Severity of postoperative pain

Timepoint

In extubation time, 15 minutes, 30 minutes, 60 minutes, 2 hours, 4 hours, 8 hours, 16 hours and 24 hours after operation

Method of measurement

Questionnaire according to Visual Analogue Scale

Secondary outcomes

1

Description

Blood pressure

Timepoint

In extubation time, 15 minutes, 30 minutes, 60 minutes, 2 hours, 4 hours, 8 hours, 16 hours and 24 hours after operation

Method of measurement

Manometer

2

Description

Pulse Rate

Timepoint

In extubation time, 15 minutes, 30 minutes, 60 minutes, 2 hours, 4 hours, 8 hours, 16 hours and 24 hours after operation

Method of measurement

Pulseoxymeter

Intervention groups

1

Description

Intervention group 1: Intravenous injection of 15mg/kg paracetamol in 20 cc normal saline

Category

Treatment - Drugs

2

Description

Intervention group 2: Intravenous injection of 0.15mg/kg metoclopramide in 20 cc normal saline

Category

Treatment - Drugs

3

Description

Intervention group 3: Intravenous injection of 0.10mg/kg metoclopramide and 10mg/kg paracetamol in 20 cc normal saline

Category

Treatment - Drugs

4

Description

Control group: Intravenous injection in 20 cc normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Medical Center, Isfahan

Full name of responsible person

Hamid Haji Gholam Saryazdi

Street address

Isfahan University of Medical Science, Hezar Jarib Street, Isfahan, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Haghjoo

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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

Esfahan 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

Esfahan University of Medical Sciences

Full name of responsible person

Hamid Haji Gholam Saryazdi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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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

Whole data will be available

When the data will become available and for how long

Immediately after publishing manuscript

To whom data/document is available

To whom is in need to this data

Under which criteria data/document could be used

Email to Dr Hamid Haji Gholam Saryazdi Email:
haji@med.mui.ac.ir

From where data/document is obtainable

Dr Hamid Haji Gholam Saryazdi

What processes are involved for a request to access data/document

Email to Dr Hamid Haji Gholam Saryazdi Email:
haji@med.mui.ac.ir

Comments