Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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, Metoclopramiode 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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hosnamirzajani@yahoo.com

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 Comittee of Isfahan University of Meical Science
Street address
Isfahan University of Medical Science, Hezar Jarib Street, Isfahan, Iran
City
Isfahan
Province
Isfehan
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 Univesity of Medical Science, Hezar Jarib Street, Isfahan,Iran
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haji@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Isfahan University of Medical Science, Hezar Jarib Street, Isfahan, Iran
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haghjoo@med.mui.ac.ir
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
Street address
Isfahan University of Medical Science, Hezar Jarib

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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