

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

Comparison of analgesic effect of intravenous Acetaminophen and Morphine on post Laparoscopic Cholecystectomy pain

Protocol summary

Study aim

Comparison of analgesic effect of intravenous acetaminophen and morphine

Design

A randomized single blind clinical trial with parallel groups

Settings and conduct

Patients undergoing laparoscopic cholecystectomy in Semnan Kosar Hospital. Patients will be provided with adequate explanations about each drug and study method before inclusion. Though, they will not know on which regimen they are.

Participants/Inclusion and exclusion criteria

Patients 20-60 years old; undergoing laparoscopic cholecystectomy ; and ASA class I and II; Other than drug addict; and sensitive to drugs used

Intervention groups

Three groups of 20 people included the intravenous acetaminophen group, the morphine group and the intravenous acetaminophen and morphine group
According to ethics, we will have no control group in control of pain

Main outcome variables

Pain control ; morphine complications reduction

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171228038117N1**

Registration date: **2018-02-07, 1396/11/18**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-07, 1396/11/18**

Update count: **0**

Registration date

2018-02-07, 1396/11/18

Registrant information

Name

Babak Hosseinzadeh zorofchi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-21, 1396/11/01

Expected recruitment end date

2019-03-21, 1398/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of analgesic effect of intravenous Acetaminophen and Morphine on post Laparoscopic Cholecystectomy pain

Public title

Comparison of analgesic effect of intravenous Acetaminophen and Morphine on post Laparoscopic Cholecystectomy pain

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients under Laparoscopic Cholecystectomy

Exclusion criteria:

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Use randomized numbers to allocate patients in 3 blocks (groups)

Blinding (investigator's opinion)

Single blinded

Blinding description

Patients will be provided with adequate explanations about each drug and study method before inclusion. Though, they will not know on which regimen they have undergone

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Semnan University of Medical Sciences

Street address

Amin Street

City

Semnan

Province

Semnan

Postal code

3515894931

Approval date

2017-12-12, 1396/09/21

Ethics committee reference number

IR.SEMUMS.REC.1396.164

Health conditions studied

1

Description of health condition studied

Post Laparoscopic Cholecystectomy pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Post operative pain

Timepoint

Before of operation; After 30 min ; 2,6 and 8 hours after the operation

Method of measurement

Numerical Rating Scale (NRS)

Secondary outcomes

1

Description

Respiratory Rate

Timepoint

30 min, 2,6 and 8 hours after the operation

Method of measurement

Patient's respiratory rate

2

Description

Pulse Rate

Timepoint

30 min, 2,6 and 8 hours after the operation

Method of measurement

Patient's Pulse Rate

3

Description

Blood Pressure

Timepoint

30 min, 2,6 and 8 hours after the operation

Method of measurement

Manometer

4

Description

Needs to additional Morphine

Timepoint

Times to need

Method of measurement

Dosage used

Intervention groups

1

Description

Intervention group 1: Morphine Sulfate 10mg produced by Daroopaksh, Intra Muscular. Repeat 3 time each 8 hours

Category

Treatment - Drugs

2

Description

Intervention group2: Intra Venus acetaminophen.
Tylophen 1g produced by Exir, in 100cc Normal Saline ,
infusion in 15 minutes. Repeat 3 time each 8 hours

Category

Treatment - Drugs

3

Description

Intervention group3: Morphine and Acetaminophen Intra
Venus. Morphine Sulfate 5mg, produced by
Daroopaksh, Intra Muscular and Tylophen 5g produced
by Exir, in 100cc Normal Saline , infusion in 7minutes.
Repeat 3 time each 8 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Kousar Hospital

Full name of responsible person

Meysam Yousofzade

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Amin Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

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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

Semnan 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

Semnan University of Medical Sciences

Full name of responsible person

Meysam Yousofzade

Position

Student(Intern)

Latest degree

A Level or less

Other areas of specialty/work

General Practitioner

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Babak Hoseinzadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

Contact
Name of organization / entity
Semnan University of Medical Sciences
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Meysam Yousofzade
Position
Student(Intern)
Latest degree
A Level or less
Other areas of specialty/work
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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