Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 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
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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 Daroopakhsh, 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 Daroopakhsh, 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
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Sponsors / Funding sources

1

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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
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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