

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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)

##### Phone

+98 23 3343 7838

##### Email address

babak.hoseinzadeh@semums.ac.ir

#### 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  
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

**Street address**

Amin Street

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**Phone**

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**Email**

m.yousofzade@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Semnan University of Medical Sciences

**Full name of responsible person**

Meysam Yousofzade

**Street address**

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**Province**

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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

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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

**Full name of responsible person**

Meysam Yousofzade

**Position**

Student(Intern)

**Latest degree**

A Level or less

**Other areas of specialty/work**

General Practitioner

**Street address**

Amin Street

**City**

Semnan

**Province**

Semnan

**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