Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

Effect of ultra-low dose Naloxone on pain intensity after laparoscopic cholecystectomy surgery

Protocol summary

Study aim
Effect of ultra-low dose Naloxone on pain intensity after laparoscopic cholecystectomy surgery
Design
Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 60 patients. In order to randomize, the block randomization method will be used.
Settings and conduct
In this research, all patients requiring laparoscopic cholecystectomy surgery, referred to Rasoul Akram Hospital in Tehran, will be included in the study. Patients will be randomly divided into 2 groups based on blocks of 4. The sample size for each study group is 30 people. A total of 60 patients will be examined. Patients, surgeon and data analyst will be blinded.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Candidate for non-emergency laparoscopic cholecystectomy surgery, Age between 30-65 years. Non-entry criteria: History of psychological illness, pregnant women, Abuse of alcohol or drugs.
Intervention groups
After the surgery, a PSA pump will be used for pain control for all patients. Intervention group: The internal composition of the PSA pump includes 20 mg of morphine mg/ml and naloxone at a dose of 0.25 µg/kg/h, it will be up to 100 cc (the total volume of the PSA pump). Control group: The internal composition of the PSA pump includes 20 mg of morphine mg/ml and , the rest of it will be up to 100 cc of normal saline inside the PCA pump. (the total volume of the PSA pump).
Main outcome variables
Severity of patients' pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20230424057986N1**
Registration date: **2023-05-18, 1402/02/28**
Registration timing: **prospective**

Last update: **2023-05-18, 1402/02/28**
Update count: **0**
Registration date
2023-05-18, 1402/02/28

Registrant information
Name
Saghar Ansari
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-06-05, 1402/03/15
Expected recruitment end date
2023-12-06, 1402/09/15
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Effect of ultra-low dose Naloxone on pain intensity after laparoscopic cholecystectomy surgery

Public title
Effect of ultra-low dose Naloxone on pain
Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for non-emergency laparoscopic cholecystectomy surgery Age between 30-65 years

Exclusion criteria:

History of psychological illness Pregnant women Abuse of alcohol or drugs

Age

From **30 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups. The randomization tool will be a random sequence generation software called SAS. In addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. Block randomization method will be used for randomization. Block randomization is for the purpose of making sure that exactly equal number of participants enter the study groups. The advantages of block randomization are that the balance of the number of participants in each group is guaranteed. For this purpose, 4 blocks will be formed and in each block, 2 people from intervention group and 2 people in control group will be placed. A total of 15 blocks will be considered to reach the sample size. The blocks contain numbers, odd numbers represent the intervention group and even numbers represent the control group. Their order will be determined by the software initially. In order to hide the random allocation, opaque envelopes sealed with a random sequence will be used. In this method, each of the generated random sequences will be recorded on a card and the cards respectively will be placed in the envelopes. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of participants, based on the order of entry of qualified participants into the study, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be blinded to the type of treatment. To hide, similar and identical serums, were used without drug name label and only with code. Patients will be aware that they will be randomly assigned to one of the two treatment groups, but will not know which treatment will be provided in that group. Patients will be assigned to one of two groups using a random number table. The person in charge of data collection, the analyst and the outcome evaluator will collect and analyze the data based on groups 1 and 2 and will not know the type of treatment provided in the groups and will be kept blind.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-02-15, 1401/11/26

Ethics committee reference number

IR.IUMS.FMD.REC.1401.659

Health conditions studied

1

Description of health condition studied

Cholecystitis

ICD-10 code

K81

ICD-10 code description

Cholecystitis

Primary outcomes

1

Description

Severity of patients' pain

Timepoint

2, 6, 12 and 24 hours after surgery

Method of measurement

Based on numerical rating scale of pain (NRS)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Intervention group: Patients with a specific anesthesia protocol that includes midazolam 0.1 mg/kg (manufacturer: Abu Rayhan), fentanyl 3 µg/kg (manufacturer: Norman S A), nesdonal 5 mg/kg (manufacturer: Co. Jaber Eban Hayan Pharmaceuticals), atracurium 0.1 mg/kg (manufacturer: Behin Tamin Roza Med Co.) at intervals of 20 to 40 minutes, and during anesthesia with isoflurane 1 MAC, they will be under general anesthesia. After the surgery, a PSA pump (Manufacturer: Pouyan Teb Tajhiz Asia Co., Ltd.) will be used for pain control for all patients. The internal composition of the PSA pump in the intervention group includes 20 mg of morphine mg/ml (manufacturer: Daro Pakhsh) and naloxone at a dose of 0.25 µg/kg/h (manufacturer: Tolid Daroo), it will be up to 100 cc (the total volume of the PSA pump).

Category
Treatment - Drugs

2

Description
Control group: Patients with a specific anesthesia protocol that includes midazolam 0.1 mg/kg (manufacturer: Abu Rayhan), fentanyl 3 µg/kg (manufacturer: Norman S A), nesdonal 5 mg/kg (manufacturer: Co. Jaber Eban Hayan Pharmaceuticals), atracurium 0.1 mg/kg (manufacturer: Behin Tamin Roza Med Co.) at intervals of 20 to 40 minutes, and during anesthesia with isoflurane 1 MAC, they will be under general anesthesia. After the surgery, a PSA pump (Manufacturer: Pouyan Teb Tajhiz Asia Co., Ltd.) will be used for pain control for all patients. The internal composition of the PSA pump in the control group includes 20 mg of morphine mg/ml (manufacturer: Daro Pakhsh) and the rest of it will be up to 100 cc of normal saline (manufacturer: Samen Pharmaceuticals) inside the PCA pump. (the total volume of the PSA pump).

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-Akram 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
Iran 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
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Iran University of Medical Sciences
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Position
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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