Clinical Trial Protocol
Iranian Registry of Clinical Trials

31 May 2026

Comparison of the role of intrapleural pethidine injection with intravenous morphine in the management of post-operative pain after open cholesystectomy

Protocol summary

Study aim

Comparison of the role of intrapleural pethidine injection with intravenous morphine in the management of post-operative pain after open cholesystectomy

Design

Randomized,controlled clinical trial, phase 3, with two arm parallel groups with blind patients, documentation and outcome assessment, sample volume of 80 patients divided into 2 groups of 40 patients

Settings and conduct

In the operating room of Loghman Hakim hospital, at the end of the surgery, in the intervention group, the neuromuscular reversal agents is administered and the infusion of propofol and remifental continues.A metallic epidural needle is inserted in the right fifth intercostal space at the midaxillary line.The correct placement of the needle within the intrapleural space is checked confirmed by the suction of water drop into the space(hanging-drop technique).The total volume of 20 milliliter of the drug is injected, which is normal saline in the control group.In this group 0.1 milligram per kilogram of body weight of morphine sulfate is injected intravenously. The injected drug in the intervention group is 50 milligram of Pethidine diluted in saline.

Participants/Inclusion and exclusion criteria

Candidates for elective open cholecystectomy;with ASA Class=1 or 2; No previous history of addiction or prolonged analgesic consumption; No history of thoracotomy

Intervention groups

Intervention group: as the postoperative management regimen, interpleural block(Hanging drop technique) by pethidine is planned; Control group: to control the postoperative pain, intravenous morphine is prescribed.For blinding, interpleural block is performed by the same volume of normal saline.

Main outcome variables

Amount of consumed morphine during the first 12 hours of postoperative period; The time of first demand for morphine during the postoperative period

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151012024493N3**
Registration date: **2019-03-10, 1397/12/19**
Registration timing: **retrospective**

Last update: **2019-03-10, 1397/12/19**
Update count: **0**

Registration date

2019-03-10, 1397/12/19

Registrant information

Name

Parissa Sezari

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 912 219 4036

Email address

psezari@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-03-21, 1397/01/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

2018-03-21, 1397/01/01

Actual recruitment end date

2018-10-23, 1397/08/01

Trial completion date

2018-10-23, 1397/08/01

Scientific title

Comparison of the role of intrapleural pethidine injection with intravenous morphine in the management of post-operative pain after open cholesystectomy

Public title

Comparison of the role of intrapleural pethidine injection with intravenous morphine in the management of post-operative pain after open cholesystectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for elective open cholecystectomy surgery ASA class = 1 or 2 BMI between 18 to 30 kg/m2

Exclusion criteria:

History of addiction History of prolonged analgesic consumption History of thoractomy

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **80**

Actual sample size reached: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Sealed envelope method: The assigned group is written on a paper within sequentially numbered, opaque, sealed envelopes. Investigators should only open the envelopes sequentially, right before the beginning of anesthesia for each patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients are not aware of the type of the applied technique. The chief researcher who is responsible for patient's safety and preparing the drugs, is aware of the techniques administered. But the resident and the nurse in the recovery ward do not know which technique has been used. The coding of the groups are numerical and the statistical analyst and the laboratory personnel are not aware of the coding type.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-chancellor in research Affairs-Shahid Beheshti university of medical sciences

Street address

7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City

Tehran

Province

Tehran

Postal code

1983963113

Approval date

2019-02-26, 1397/12/07

Ethics committee reference number

IR.SBMU.MSP.REC.1397.792

Health conditions studied

1

Description of health condition studied

Open cholecystectomy

ICD-10 code

K81

ICD-10 code description

Cholecystitis

Primary outcomes

1

Description

Amount of consumed morphine during the first 12 hours of postoperative period

Timepoint

12 hours after surgery

Method of measurement

Documented total amount of injected morphine in milligrams

2

Description

The time of first demand for morphine during the postoperative period

Timepoint

The time of first patient's demand for morphine during the postoperative period in minutes

Method of measurement

chronometer

Secondary outcomes

empty

Intervention groups

1

Description

Control group: At the end of the surgery,the patient receives the neuromuscular reversal agents and the infusion of propofol and remifental continues.A metallic epidural needle is inserted in the right fifth intercostal space at the midaxillary line.The correct placement of the needle within the intrapleural space is checked confirmed by the suction of water drop into the space(hanging-drop technique).The total volume of 20 milliliter of the drug is injected, which is normal saline in the control group.In this group 0.1 milligram per kilogram of body weight of morphine sulfate is injected intravenously.

Category

Treatment - Other

2

Description

Intervention group: At the end of the surgery,the patient receives the neuromuscular reversal agents and the infusion of propofol and remifental continues.A metallic epidural needle is inserted in the right fifth intercostal space at the midaxillary line.The correct placement of the needle within the intrapleural space is checked confirmed by the suction of water drop into the space(hanging-drop technique).The total volume of 20 milliliter of the drug is injected, which in the intervention group is 50 milligram of Pethidine diluted in saline.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Loghman Hakim hospital

Full name of responsible person
Parisa Sezari

Street address
Loghman Hakim hospital, Makhsus St., South Kargar Ave., Tehran

City
Tehran

Province
Tehran

Postal code
13333631151

Phone
+98 21 5542 4040

Email
parissasezari@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Parisa Sezari

Street address
7th Floor, Bldg No.2 SBUMS, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehran

Province
Tehran

Postal code
1983963113

Phone
+98 21 23871

Email
info@sbmu.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parisa Sezari

Position
Assisstant profrssor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Loghman Hakim hospital, Makhsus St., South Kargar Ave., Tehran

City
Tehran

Province
Tehran

Postal code

1333631151

Phone
+98 21 5542 4040

Email
parissasezari@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Parisa Sezari

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Email
parissasezari@yahoo.com

Person responsible for updating data

Contact

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Shahid Beheshti University of Medical Sciences

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Parisa Sezari

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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
Not applicable

Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report
Not applicable

Analytic Code
Not applicable

Data Dictionary
Not applicable