

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparative study of the effect of sufentanil and lidocaine mixture in comparison with morphine and lidocaine mixture in the prevention of hypertension and tachycardia in patients under general anesthesia in Khatam Al-Anbia hospital in Shahrud in 1399_1400

Protocol summary

Study aim

Comparative study of the effect of sufentanil and lidocaine mixture in comparison with morphine and lidocaine mixture in the prevention of hypertension and tachycardia in patients under general anesthesia

Design

Patients are divided into two equal groups of 50 based on even and odd numbers. For group A, we inject the combination of sufentanil with lidocaine, and for group B, inject morphine with lidocaine, and measure and record their blood pressure and heart rate 15 times, one minute before the injection and zero (immediately after the injection), 5, 10, and 20 minutes after the injection. The anesthesiologist is in charge of the project. Then data will be analyzed.

Settings and conduct

The present study will be a clinical trial that will be conducted in Khatam Al-Anbia Hospital in Shahrud in 1399-1400 in the operating room. Sample size: According to Morgan sample size table, we will consider a community of 140 patients, which based on this table, the sample size will be equal to 100 people.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate patients for laparoscopic cholecystectomy with general anesthesia; minimum age 18 years and maximum age 65 years; informed consent. Exclusion criteria: patients with hypertension; cesarean section; history of any cardiovascular disease including HTN CHF, IHD; history of any diagnostic (invasive) and therapeutic procedures on the heart, such as angiography and surgery.

Intervention groups

Group A injects sufentanil with lidocaine and group B injects morphine with lidocaine.

Main outcome variables

Systolic blood pressure, mean and mean and heart rate.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210807052100N1**

Registration date: **2021-09-03, 1400/06/12**

Registration timing: **retrospective**

Last update: **2021-09-03, 1400/06/12**

Update count: **0**

Registration date

2021-09-03, 1400/06/12

Registrant information

Name

navid panahi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8802 6180

Email address

navid.pan.np@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-20, 1399/11/01

Expected recruitment end date

2021-06-20, 1400/03/30

Actual recruitment start date

2021-01-20, 1399/11/01

Actual recruitment end date

2021-06-20, 1400/03/30

Trial completion date

2021-06-20, 1400/03/30

Scientific title

Comparative study of the effect of sufentanil and lidocaine mixture in comparison with morphine and lidocaine mixture in the prevention of hypertension and tachycardia in patients under general anesthesia in Khatam Al-Anbia hospital in Shahroud in 1399_1400

Public title

Comparative effect of sufentanil over morphine in the prevention of hypertension and tachycardia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate for laparoscopic cholecystectomy Age between 18 and 65 years

Exclusion criteria:

Having high blood pressure Cesarean History of heart disease including CHF, IHD. COPD Allergy to opium Asthma History of invasive diagnostic and therapeutic action on the heart

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **100**

Actual sample size reached: **100**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

By taking different medications on odd and even days without notifying the patient about their group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Sharood Azad Islamic University of Medical Sciences

Street address

University Boulevard, Khatam Al-Anbia hospital, Shahroud

City

Shahroud

Province

Semnan

Postal code

3614871151

Approval date

2020-12-27, 1399/10/07

Ethics committee reference number

IR. IAU. SHAHROOD. REC. 1399. 052

Health conditions studied

1

Description of health condition studied

Cholecystitis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Blood pressure changes

Timepoint

In !5 minutes before, zero and after 5, 10 and 20 minutes

Method of measurement

Cardiac monitoring of blood pressure and heart rate

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: -Sofentanil: 0.06-0.05 mg per kg body weightLidocaine: 1-2 mg per kg body weight.

Category

Treatment - Drugs

2

Description

Intervention group 2: Lidocaine: 1-2 mg/kg, Morphine: 2-3 mg/kg

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatamalanbia hospital

Full name of responsible person

Yusef Kolukhi

Street addressUniversity Boulevard; Khatam Al-Anbia hospital;
Shahrud**City**

Shahrud

Province

Semnan

Postal code

3614871151

Phone

+98 23 3239 2661

Email

Navid.pan.np@gmail.com

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Dr Yusef Kolukhi

Street addressUniversity Boulevard in front of Khatam Al-Anbia
Hospital, Shahrud**City**

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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

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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**

Islamic Azad University

Full name of responsible person

Dr Yusef Kolukhi

Position

Attend

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street addressUniversity Boulevard, in front of the University of
Technology, Khatam Al-Anbia 100-bed hospital**City**

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

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Position

Attend

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data**Contact****Name of organization / entity**

Islamic Azad University

Full name of responsible person

Navid Panahi

Position

Medical student

Latest degree

A Level or less

Other areas of specialty/work

Anesthesiology

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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

Not applicable

Data Dictionary

Not applicable