

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

The effect of bupivacaine (Marcaine) intraperitoneal instillation on pain reduction after open hysterectomy surgery.

Protocol summary

Study aim

Determination of the effect of bupivacaine intraperitoneal instillation on pain reduction after hysterectomy surgery

Design

A randomized, triple-blinding clinical trial, with parallel groups, Phase 3 on 110 patients

Settings and conduct

In this three-blind randomized clinical trial study, 110 eligible patients, referred to Al-Zahra and Beheshti hospitals in Isfahan, will be included in the study and will be randomly divided into two groups. After surgery, before closing the peritoneum, 40 ml of bupivacaine 0.25% in the first group and 40 ml of normal saline in the second group will be sprayed into the peritoneal cavity. The intervention will be performed in such a way that the patient, the researcher and the statistical analyst will not have any knowledge of the type of intervention. Then the severity of pain and hemodynamic parameters of the patients will be compared between the two groups.

Participants/Inclusion and exclusion criteria

The inclusion criteria include women who are candidates for hysterectomy surgery, in the age range of 18 to 65 years, with ASA class one and two, no history of allergy to the drugs used (bupivacaine or morphine), no underlying disease (such as asthma, other chronic diseases) and consent to participate in the study. The exclusion criteria is drug use (having an addiction).

Intervention groups

Intervention group: In this group, 40 ml of bupivacaine 0.25% is sprayed into the peritoneal cavity. Control group: In this group, 40 ml of normal saline will be sprayed into the peritoneal cavity.

Main outcome variables

Systolic blood pressure, diastolic blood pressure, heart rate, oxygen saturation(Spo2); Severity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200825048515N66**

Registration date: **2023-04-24, 1402/02/04**

Registration timing: **prospective**

Last update: **2023-04-24, 1402/02/04**

Update count: **0**

Registration date

2023-04-24, 1402/02/04

Registrant information

Name

Asieh Maghami Mehr

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 0000 0000

Email address

asimaghami@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-05-21, 1402/02/31

Expected recruitment end date

2024-01-21, 1402/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of bupivacaine (Marcaine) intraperitoneal instillation on pain reduction after open hysterectomy surgery.	
Public title	The effect of bupivacaine on pain reduction after hysterectomy surgery.
Purpose	Treatment
Inclusion/Exclusion criteria	Inclusion criteria: Women candidates for hysterectomy surgery Age range from 18 to 65 years Having ASA class one and two No history of allergy to the drugs used (bupivacaine or morphine) Not having an underlying disease (such as asthma, other chronic diseases) Consent to participate in the study Exclusion criteria: Drug use (having an addiction)
Age	From 18 years old to 65 years old
Gender	Female
Phase	3
Groups that have been masked	• Participant • Care provider • Investigator • Data analyser
Sample size	Target sample size: 110
Randomization (investigator's opinion)	Randomized
Randomization description	Before starting the study, letter A is written on 55 sheets, letter B is written on 55 sheets, and each is placed in an envelope. Then, each eligible patient who consented to participate in the study is asked to choose an envelope from among the envelopes. In this way, the patient will be randomly assigned to one of the two groups according to the envelope selected without the interference of the researcher.
Blinding (investigator's opinion)	Triple blinded
Blinding description	In order to comply with the condition of triple-blindness of the study, two drugs, bupivacaine and normal saline, will be prepared by the operating room nurse (without the knowledge of the researcher) in equal volumes (40 mg) in syringes covered with labels A, B and will be prepared and placed in the bag daily. And it is given to the researcher daily. Therefore, the researcher, the patient, the person recording the clinical and basic information of the patients, as well as the statistical analyst, will not be aware of the type of intervention.
Placebo	Used
Assignment	Parallel
Other design features	

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Isfahan University of Medical Sciences

Street address

Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City

Isfahan

Province

Isfahan

Postal code

8179964167

Approval date

2022-10-14, 1401/07/22

Ethics committee reference number

IR.MUI.MED.REC.1401.262

Health conditions studied

1

Description of health condition studied

Hysterectomy surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Systolic blood pressure

Timepoint

Before surgery, immediately after surgery, (in the first hour after surgery, every 15 minutes, in the second hour, every 30 minutes, and then at 8, 6, 4, 3, 2 hours) after surgery

Method of measurement

Monitoring device

2

Description

Diastolic blood pressure

Timepoint

Before surgery, immediately after surgery, (in the first hour after surgery, every 15 minutes, in the second hour, every 30 minutes, and then at 8, 6, 4, 3, 2 hours) after surgery

Method of measurement

Monitoring device

3

Description

Heart beat

Timepoint

Before surgery, immediately after surgery, (in the first hour after surgery, every 15 minutes, in the second hour, every 30 minutes, and then at 8, 6, 4, 3, 2 hours) after surgery

Method of measurement

Monitoring device

4

Description

Oxygen saturation (SPO2)

Timepoint

Before surgery, immediately after surgery, (in the first hour after surgery, every 15 minutes, in the second hour, every 30 minutes, and then at 8, 6, 4, 3, 2 hours) after surgery

Method of measurement

Monitoring device

5

Description

Severity of pain

Timepoint

Before surgery, immediately after surgery, (in the first hour after surgery, every 15 minutes, in the second hour, every 30 minutes, and then at 8, 6, 4, 3, 2 hours) after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After surgery, before closing the peritoneum, 40 ml of bupivacaine 0.25% is sprayed into the peritoneal cavity.

Category

Treatment - Drugs

2

Description

Control group: After surgery, before closing the peritoneum, 40 ml of normal saline will be sprayed into the peritoneal cavity.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Alireza Hoghooghi

Street address

Soffe Blvd, Isfahan

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alireza.hoghooghi@gmail.com

2

Recruitment center

Name of recruitment center

Shahid Beheshti Hospital

Full name of responsible person

Alireza Hoghooghi

Street address

Motahari Street.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3234 6338

Email

alireza.hoghooghi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Gholamreza Askari

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfahan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Alireza Hoghooghi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City
Isfahan

Province
Isfahan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
alireza.hoghooghi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Alireza Hoghooghi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address

Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City

Isfahan

Province

Isfahan

Postal code

8174675731

Phone

+98 31 3620 2020

Email

alireza.hoghooghi@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mohammad Jafari

Position
Non-faculty specialist doctor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City
Isfahan

Province
Isfahan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
m.jafary۸۰۷۴@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available