

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of subcutaneous in trocar site and intraperitoneal and posterior transverses abdominis plan block under laparoscopic guide with bupivacaine on post laparoscopic pain in laparoscopic hysterectomy

Protocol summary

Study aim

Comparison of subcutaneous injection at the trocar site, intraperitoneal injection and transverse abdominis plan block under laparoscopic guidance with bupivacaine 0.25% in reducing abdominal pain and shoulder pain after laparoscopic hysterectomy.

Design

A phase 3 randomized controlled double-blinded clinical trial, with parallel groups, of 95 patients. For randomization, the block randomization method and STATA software will be used.

Settings and conduct

The study is conducted in a double-blind manner, in such a way that none of the patients and the pain evaluator know about the method of analgesia after laparoscopic hysterectomy surgery, and as a result, the study is conducted in a double-blind manner. Abdominal and shoulder pain score using VISUAL-ANALOGUE-SCALE during the first 2-4 hours after surgery. 8 hours. It is measured 12 hours and 24 hours after surgery. Scoring is done with the help of nurses in the post-surgery department without their knowledge of the applied anesthesia method. Complications after surgery. The amount of drug use. The amount of Morphine and Ketorolac ampoules used. Nausea and vomiting after surgery are recorded.

Participants/Inclusion and exclusion criteria

All patients who are candidates for elective laparoscopic hysterectomy referred to Arash Hospital who have a good general health level based on ASA Grade 1&2 and are candidates for hysterectomy due to benign disease. Patients suffering from chronic pelvic pain, pregnancy, sensitivity to bupivacaine, emergency surgery, cancer are excluded from the study.

Intervention groups

The three intervention groups: subcutaneous injection of bupivacaine 0.25%, intraperitoneal injection and

posterior transverse abdominis block, and the control group.

Main outcome variables

Abdominal pain; shoulder pain; need for narcotics; need for painkillers; nausea and vomiting decrease after laparoscopic hysterectomy.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110530006640N9**

Registration date: **2022-09-11, 1401/06/20**

Registration timing: **registered_while_recruiting**

Last update: **2022-09-11, 1401/06/20**

Update count: **0**

Registration date

2022-09-11, 1401/06/20

Registrant information

Name

Zahra Asgari

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-07, 1401/05/16

Expected recruitment end date

2022-11-11, 1401/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of subcutaneous in trocar site and intraperitoneal and posterior transverses abdominis plan block under laparoscopic guide with bupivacaine on post laparoscopic pain in laparoscopic hysterectomy

Public title

The effect of bupivacaine on post laparoscopic pain in laparoscopic hysterectomy with the three way of injection (subcutaneous in trocar site and intraperitoneal and posterior transverses abdominis plan block under laparoscopic guide)

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

All candidates for elective laparoscopic hysterectomy surgery referred to Arash Hospital Have a good general health level based on ASA Grade 1&2. Candidates for hysterectomy due to benign disease.

Exclusion criteria:

Patients who suffered from chronic pelvic pain (non menstrual pain of 6 or more months) Pregnancy Allergy to Bupivacaine hydrochloride Emergency surgeries Execution of additional vaginal procedures Surgeries performed for following indication :active pelvic infection, ectopic pregnancy , or malignancy Patients with conversion laparoscopy to laparotomy and intraoperative diagnosis of malignancy (confirmed by frozen section pathology)

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: 95

Randomization (investigator's opinion)

Randomized

Randomization description

For the randomization process, the balance block randomization method is used using STATA software. To ensure that the randomization process of people in the groups remains hidden, the randomized sequence is kept with one of the project researchers, who is part of the selection team. Patients and carrying out the

intervention process and evaluating the outcome are not.

Blinding (investigator's opinion)

Double blinded

Blinding description

For the randomization process, the balance block randomization method is used using STATA software. To ensure that the randomization process of people in the groups remains hidden, the randomized sequence is kept with one of the project researchers, who is part of the selection team. Patients and carrying out the intervention process and evaluating the outcome are not. The study is conducted in a double-blind manner, in such a way that none of the patients and the pain evaluator know about the method of analgesia after laparoscopic hysterectomy surgery. Analgesia is injected by laparoscopic fellowship doctors half an hour before the end of anesthesia induction. Procedure selection envelopes are with the operator of the operating room, and one envelope is randomly delivered to the laparoscopic fellowship for anesthesia.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of school medicine, Tehran University of Medical Sciences

Street address

Tehran University of Medical Science, Poursina St., Keshavarz Blvd.

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Province

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Postal code

1417653761

Approval date

2022-04-06, 1401/01/17

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1401.020

Health conditions studied**1****Description of health condition studied**

Pain after laparoscopic hysterectomy surgery

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Abdominal pain and shoulder pain

Timepoint

2-4 hours , 8 h , 12 h , 24 h , after surgery

Method of measurement

With Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: subcutaneous injection of 10cc bupivacaine 0.25% /Heavy under trocar sites

Category

Treatment - Drugs

2

Description

Intervention group: 10cc Bupivacaine 0.25% /Heavy injection into the Transvers abdominis plan block

Category

Treatment - Drugs

3

Description

Intervention group:10cc Bupivacaine 0.25%/Heavy intraperitoneal injection

Category

Treatment - Drugs

4

Description

Control group: No injection of bupivacaine 0.25% to any of the intervention methods

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women Hospital

Full name of responsible person

Dr. Zahra Asgari

Street address

Arash Women Hospital, Corner of 162 Alley (Shahid Abdolmajid), Next to Police Station 126, Shahid Baghdarnia Street (North Rashid), After Shahid

Bagheri Highway, Resalat Highway.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotohi

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Keshavarz Boulevard, Quds Street

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Zahra Asgari

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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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