Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Morphin 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

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Zahra Asgari
Name of organization / entity
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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 withe 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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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
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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