Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jul 2026

Investigating the effect of ultrasound- guided bilateral dual transverse abdominal plane block (TAP) and erector spine plane block on the postoperative quality of recovery after total abdominal hysterectomy

Protocol summary

Study aim

Investigating the effect of ultrasound- guided bilateral dual transverse abdominal plane block (TAP) and erector spine plane block on the postoperative quality of recovery after total abdominal hysterectomy

Design

Clinical trial with control group, parallel groups, double-blind, randomized, phase 3 on 40 patients. In order to randomize, the block randomization method will be used.

Settings and conduct

In this research, all patients requiring total abdominal hysterectomy surgery, referred to Firouzgar and Rasoul Akram Hospitals in Tehran, will be included in the study.Patients will be randomly divided into 2 groups based on blocks of 6. The sample size for each study group is 30 people. A total of 60 patients will be examined. Patients, surgeon and data analyst will be blinded.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Women with uterine diseases and candidates for full abdominal hysterectomy Age between 20-60 years A person with normal health A person with mild systemic disease Non-entry criteria: Allergy to any of the drugs used in the study Addiction to alcohol, benzodiazepines and narcotics The presence of underlying diseases including kidney disease, liver disease, heart failure, arrhythmia or valvular heart disease Coagulation disorder Contraindications for regional anesthesia Emergency patients Patients who have received analgesics in the last 24 hours

Intervention groups

Intervention group 1: In patients with bilateral erector spinae plate block, at the T9 level of the lumbar vertebra, 20 cc of ropivacaine 0.2% will be used bilaterally. Intervention group 2: In the bilateral dual transverse abdominal plane block (TAP) group, on each side two injections, one in the umbilical alignment and the other subcostal, 15 cc of ropivacaine 0.2% will be used.

Main outcome variables

Severity of patients' pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230424057986N2**
Registration date: **2023-06-08, 1402/03/18**
Registration timing: **prospective**

Last update: **2023-06-08, 1402/03/18**
Update count: **0**

Registration date

2023-06-08, 1402/03/18

Registrant information

Name

Saghar Ansari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2255 9577

Email address

ansarisaghar@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-27, 1402/04/06

Expected recruitment end date

2023-11-22, 1402/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of ultrasound- guided bilateral dual transverse abdominal plane block (TAP) and erector spine plane block on the postoperative quality of recovery after total abdominal hysterectomy

Public title

Investigating the effect of ultrasound- guided bilateral dual TAP block and erector spine plane block

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Women with uterine diseases and candidates for full abdominal hysterectomy Age between 20-60 years A person with normal health A person with mild systemic disease

Exclusion criteria:

Allergy to any of the drugs used in the study Addiction to alcohol, benzodiazepines and narcotics The presence of underlying diseases including kidney disease, liver disease, heart failure, arrhythmia or valvular heart disease. Coagulation disorder Contraindications for regional anesthesia Emergency patients Patients who have received analgesics in the last 24 hours

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be randomly divided into two groups. The randomization tool will be a random sequence generation software called SAS. In addition to simple randomization, these random sequence generation software are capable of generating random sequence by block method. Block randomization method will be used for randomization. Block randomization is for the purpose of making sure that exactly equal number of participants enter the study groups. The advantages of block randomization are that the balance of the number of participants in each group is guaranteed. For this purpose, 6 blocks will be formed and in each block, 3 people from first intervention group and 3 people in second intervention group will be placed. A total of 10 blocks will be considered to reach the sample size. The blocks contain numbers, odd numbers represent the first intervention group and even numbers represent the second intervention group. Their order will be determined by the software initially. In order to hide the random allocation, opaque envelopes sealed with a random sequence will be used. In this method, each of the generated random sequences will be recorded on a card and the cards respectively will be placed in the envelopes. In order to maintain a random sequence, the outer surface of the envelopes is numbered in the same order. Finally, the lid of the letter envelopes is glued and placed in a box. At the time of registration of participants, based on the order of entry of qualified participants into the study, one of the envelopes will be opened in order and the assigned group of that participant will be revealed.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be blinded to the type of block. Patients will be aware that they will be randomly assigned to one of the two treatment groups, but will not know which block will be provided in that group. Patients will be assigned to one of two groups using a random number table. The person in charge of data collection, the analyst and the outcome evaluator will collect and analyze the data based on groups 1 and 2 and will not know the type of treatment provided in the groups and will be kept blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-04-16, 1402/01/27

Ethics committee reference number

IR.IUMS.FMD.REC.1402.025

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
G89
ICD-10 code description
Pain

Primary outcomes

1

Description
Severity of patients' pain
Timepoint
1, 2, 4, 8, 12 and 24 hours after surgery
Method of measurement
Based on visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In patients with bilateral erector spinae plate block, at the T9 level of the lumbar vertebra, 20 cc of ropivacaine 0.2% will be used bilaterally (5 mg/ml) (manufacturer: Ropivacaine Molteni) (40 cc of ropivacaine 0.2% in total). The ultrasound probe used in this group will be a curve probe in a lateral position.
Category
Treatment - Other

2

Description
Intervention group: In the bilateral dual transverse abdominal plane block (TAP) group, on each side two injections, one in the umbilical alignment and the other subcostal, 15 cc of ropivacaine 0.2% (5 mg/ml) (manufacturer: Ropivacaine Molteni) (total 60 CC ropivacaine 0.2%) will be used. The ultrasound probe used in this group will be a linear probe in the supine position.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Rasoul-Akram Hospital
Full name of responsible person
Saghar Ansari
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2

Recruitment center
Name of recruitment center
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Full name of responsible person
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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

Iran 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
Iran University of Medical Sciences

Full name of responsible person
Hamid Reza Feiz

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

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Resident

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Medical doctor

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
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