

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 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

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Email address

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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

Firouzgar hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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
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Full name of responsible person
Hamid Reza Feiz
Position
Professor
Latest degree
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Other areas of specialty/work
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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