Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Evaluation of Postoperative Analgesic Efficacy of Transversus Abdominis Plane Block After Appendectomy: A Controlled Clinical Trial Study

Protocol summary

Study aim
determinaton of the analgesic effect of transversus abdominis plane block following appendectomy

Design
A single-center, two-arm, parallel-group, randomized, active-controlled, double-blind clinical trial will be conducted at Imam Reza Hospital in Birjand, Iran. The target sample size is 60 patients, with a target of 30 patients per group. Patients will be assigned to either a TAP block with ropivacaine or intravenous pethidine using simple computer-generated randomization with equal allocation probabilities (1:1). Participants and data analysts will be blinded to group allocation.

Settings and conduct
Single-center, two-arm, parallel-group, randomized, active-controlled, double-blind clinical trial will be conducted at Imam Reza Hospital in Birjand, Iran

Participants/Inclusion and exclusion criteria
include: age over 15,asa score 1 and 2
exclude:perforation,appendicitis with hernia,bowel surgery,gyno surgery with appendectomy, age under 15

Intervention groups
The intervention group will receive a single ultrasound-guided, right-sided lateral transversus abdominis plane (TAP) block administered by an anesthesiologist at the end of open appendectomy, before emergence from anesthesia. Twenty milliliters of 0.25% ropivacaine will be injected between the internal oblique and transversus abdominis muscles. The control group will receive 25 mg of intravenous pethidine before transfer to the recovery room. Rescue analgesia will be provided as needed in both groups according to the study protocol.

Main outcome variables
Pain intensity will be measured using the Numerical Rating Scale at 1, 2, 6, 12, and 24 hours after surgery. Nausea and vomiting, adverse events, time to the first request for analgesia, and analgesic consumption will be recorded during the first 24 hours. Rescue analgesia will be provided as needed in both groups according to the protocol

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20260517069425N1**
Registration date: **2026-10-31, 1405/08/09**
Registration timing: **registered_while_recruiting**

Last update: **2026-10-31, 1405/08/09**
Update count: **0**

Registration date
2026-10-31, 1405/08/09

Registrant information

Name
amirabbas esmaeilbeigi mahani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 34 3245 0943

Email address
a.esmaeilbeigi@bums.ac.ir

Recruitment status
recruiting

Funding source

Expected recruitment start date
2026-09-23, 1405/07/01

Expected recruitment end date
2026-12-21, 1405/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Evaluation of Postoperative Analgesic Efficacy of Transversus Abdominis Plane Block After Appendectomy: A Controlled Clinical Trial Study

Public title
Evaluation of Postoperative Analgesic Efficacy of Transversus Abdominis Plane Block After Appendectomy

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 15 years ASA score 1 and 2

Exclusion criteria:
perforation appendicitis with hernia bowel surgery gynecology surgery with appendectomy age under 15

Age
From **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Data analyser

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be performed at the individual patient level using simple computer-generated randomization, with an equal probability of assignment to either the intervention or control group. No blocking or stratification will be used. Before participant recruitment, an independent researcher who is not involved in participant enrollment or intervention delivery will generate the allocation sequence using a computerized pseudorandom number generator. For each position in the sequence, the program will independently generate either code 1 or code 2 with equal probability. Allocation concealment will be maintained using sequentially numbered, opaque, sealed envelopes prepared according to the generated sequence by the independent researcher. Each envelope will contain one group assignment. After eligibility has been confirmed, written informed consent obtained, and baseline information recorded, each participant will receive the next sequential study number. The participant’s identifying details will be recorded on the corresponding envelope before it is opened. The envelope will then be opened by the anesthesiologist when the assigned intervention is due. Personnel responsible for participant enrollment will have no access to the allocation sequence or unopened assignments.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted as a double-blind trial, with participants and data analysts blinded to group allocation. Both groups will undergo general anesthesia. Participants in the intervention group will receive a TAP block at the end of surgery before emergence from anesthesia, while participants in the control group will receive intravenous pethidine before transfer to the recovery room. Participants will not be informed of their assigned intervention. The anesthesiologist administering the intervention will be aware of group allocation. Statistical analyses will be performed without disclosing the treatment identity of each group to the data analysts.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
ethics committee of birjand univercity of medical sciences

Street address
kerman,24th azar st,17th alley,NO 15

City
birjand

Province
South Khorasan

Postal code
7619745459

Approval date
2025-12-24, 1404/10/03

Ethics committee reference number
ir.bums.rec.1404.401

Health conditions studied

1

Description of health condition studied
Appendicitis

ICD-10 code
K35

ICD-10 code description
Acute appendicitis

2

Description of health condition studied
Acute postprocedural pain

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
pain score
Timepoint
1,2,6,12 and 24 hours post surgery
Method of measurement
NRS

Secondary outcomes

1

Description
postoperative nausea/vomiting
Timepoint
At 1, 2, 6, 12, and 24 hours after completion of surgery.
Method of measurement
Patient-reported nausea

2

Description
Time from completion of surgery to the first request for rescue analgesia
Timepoint
At the first request for rescue analgesia during the first 24 hours after completion of surgery.
Method of measurement
Recording the time of surgery completion and the time of the patient's first request for rescue analgesia on the data collection form

3

Description
Cumulative postoperative opioid analgesic consumption
Timepoint
Cumulatively over the first 24 hours after completion of surgery
Method of measurement
Recording the name, route of administration, and dose of each opioid analgesic administered during the first 24 postoperative hours on the data collection form

Intervention groups

1

Description
Intervention group (Transversus abdominis plane block with ropivacaine): At the end of open appendectomy, before emergence from general anesthesia, participants will receive a single right-sided transversus abdominis plane block administered by an anesthesiologist under ultrasound guidance using a lateral approach. Twenty milliliters of 0.25% ropivacaine will be injected between the internal oblique and transversus abdominis muscles.
Category
Treatment - Drugs

2

Description
Control group (Intravenous pethidine): Following open appendectomy under general anesthesia, participants will receive a single dose of 25 mg of intravenous pethidine before transfer to the recovery room.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Amirabbas Esmaeilbeigi Mahani
Street address
Taleghani st
City
Birjand
Province
South Khorasan
Postal code
9714811151
Phone
+98 56 3222 6776
Email
amires1375@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
amirabbas esmaeilbeigi mahani
Street address
imam raza hospital
City
birjand
Province
South Khorasan
Postal code
9717853577
Phone
+98 34 3245 0943
Email
amires1375@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Birjand 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
Birjand University of Medical Sciences
Full name of responsible person
amirabbas esmaeilbeigi mahani
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
24th azar st,17 th alley, NO 15
City
kerman
Province
Kerman
Postal code
7619745549
Phone
+98 34 3245 0943
Email
amires1375@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
mohammadreza ghasemian
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
General Surgery
Street address
birjand.taleghani st,imam reza hospital
City
birjand
Province
South Khorasan
Postal code
1451451515
Phone
+98 56 3239 5812
Email
dr.ghasemian54@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Birjand University of Medical Sciences
Full name of responsible person
amirabbas esmaeilbeigi mahani
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
General Surgery
Street address
24th azar
City
kerman
Province
Kerman
Postal code
7619745549
Phone
+98 34 3245 0943
Email
amires1375@gmail.com

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