Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative study of the effect of rupivacaine 0.2 and bupivacaine 0.2 in the transversus abdominis plane block (TAP) under ultrasound guidance in management of acute pain after open appendectomy (Clinical Trial)

Protocol summary

Study aim
Comparison of the effect of rupivacaine 0.2% and bupivacaine 0.2% in ultrasonically guided transverse abdominal muscle block in the control of acute pain after open appendectomy

Design
A randomized double-blind clinical trial, two groups of 26; intervention: TAP block with rupivacaine 0.2% and control TAP block with bupivacaine 0.2%.randomized using the random numbers table:

Settings and conduct
Candidates for open appendectomy referred to Shahid Madani Hospital in Karaj will be randomly divided into two groups of 26 randomly in one of the intervention / control groups.

Participants/Inclusion and exclusion criteria
This study will be performed on patients with open appendectomy referred to Shahid Madani Hospital in Karaj in 2021-2022 and patients with coagulation disorders, chronic abdominal pain and substance and alcohol abuse will not be included in the study.

Intervention groups
Intervention group: These patients receive 20 ml of rupivacaine 0.2% and develop TAP block under ultrasound guide. Control group: These patients receive 20 ml of bupivacaine 0.2% and develop TAP block under ultrasound guide.

Main outcome variables
Pain

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20211112053042N1**
Registration date: **2021-11-23, 1400/09/02**
Registration timing: **prospective**

Last update: **2021-11-23, 1400/09/02**
Update count: **0**

Registration date
2021-11-23, 1400/09/02

Registrant information

Name
Mohammad Hossein Delshad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 26 3350 2347

Email address
m.delshad@abzums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-12-05, 1400/09/14

Expected recruitment end date
2022-01-19, 1400/10/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparative study of the effect of rupivacaine 0.2 and bupivacaine 0.2 in the transversus abdominis plane block (TAP) under ultrasound guidance in management of acute pain after open appendectomy (Clinical Trial)

Public title

Comparison of the effect of rupivacaine 0.2 and bupivacaine 0.2 in the transversus abdominis plane block (TAP) under ultrasound guidance in management of acute pain after open appendectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age 18 to 60 years Patients with consent to participate in the project

Exclusion criteria:

Coagulation disorders Chronic abdominal pain Substance and alcohol abuse Dissatisfaction with participating in the project

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are divided into two groups based on a table of random numbers. Random number table is a set of numbers that are produced without a specific pattern or order and in a completely random manner and become a table. In order to use a random number table, the researcher must first predetermine the table to read the numbers (for example, up, down, left, or right). Individual for the control group). The researcher then touches one of the numbers and moves in one of the predetermined directions and records the numbers and assigns them to different groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patients (intervention or control) will receive encoded sealed envelopes. The coding will be done by one of the project partners and the doctor, the evaluator and the patient will be blind.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

second floor, Deputy of Research and Technology, Saffarian Alley, 45 meters from Golshahr, Karaj.

City

Karaj

Province

Alborz

Postal code

3149779453

Approval date

2021-08-24, 1400/06/02

Ethics committee reference number

IR.ABZUMS.REC.1400.180

Health conditions studied

1

Description of health condition studied

Acute pain after open appendectomy

ICD-10 code

G89. 18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes

1

Description

Intensity of pain

Timepoint

2, 4, 6, 8, 12, 24 and 48 hours after transverse abdominal muscle block

Method of measurement

Ask the patient based on the visual analog scale (0= No pain, 1-3=Mild, 4-7= Moderate, 8-10=Severe)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: These patients will receive 20 ml of rupivacaine 0.2% and develop TAP block under ultrasound guide.

Category

Prevention

2

Description

Control group: These patients will receive 20 ml of bupivacaine 0.2% and develop TAP block under ultrasound guide.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Madani Hospital

Full name of responsible person
Mohammad Hossein Delshad MD.

Street address
Shahid Madani Square, Jahanshahr, Karaj

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31437 44693

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+98 26 3442 7001

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m.delshad@abzums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Karaj University of Medical Sciences

Full name of responsible person
Hatam Godini P.H.D

Street address
Saffarian alley, 45 meters from Golshahr, Karaj

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Phone
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Email
h.godini@abzums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Karaj 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
Karaj University of Medical Sciences

Full name of responsible person
Mohammad Hossein Delshad MD.

Position
Assistant professor

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

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Arghavan Gharbi, 45 meters from Golshahr Street, Karaj, Alborz Province

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Mohammad Hossein Delshad MD.

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is a plan to make this available

Statistical Analysis Plan
Yes - There is 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
Yes - There is 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
Yes - There is a plan to make this available

Title and more details about the data/document
All data is potentially shareable after unidentified individuals.

When the data will become available and for how long
Access period starts 6 months after the results are published.

To whom data/document is available
Research centers and faculty members

Under which criteria data/document could be used
At the request of the researcher and faculty members

From where data/document is obtainable
Send email to the scientific respondent

What processes are involved for a request to access data/document
Within two months from the time of requesting and sending the email, the documents will be sent to the mentioned people

Comments