

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of Transversus Abdominis Plane(TAP) Block on pain control after open Appendectomy in uncomplicated acute appendicitis

Protocol summary

Study aim

Effect of Transversus Abdominis Plane(TAP) Block on pain control after open Appendectomy in uncomplicated acute appendicitis

Design

This study is clinical trial and double blind. A total of 64 candidate for non-complicated appendectomy surgery in Valiasr hospital, in Arak. We will divide patients in 2 groups by simple randomization. Groups are parallel.

Settings and conduct

This study is clinical trial and double blind. A total of 64 candidate for non-complicated appendectomy surgery in Valiasr hospital, in Arak. Outcome assessor and analyzer don't aware from grouping.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ages 18 to 65 years, no underlying disease, surgery less than one hour, no addiction, absence of connective tissue disease, absence of rheumatic disease, diagnosis of uncomplicated acute appendicitis Exclusion criteria: patients with perforated appendicitis, ovarian cyst rupture, tubo ovarian abscess

Intervention groups

In intervention group, we place the probe in the abdominal wall on the mid-axillary line between the lower ribs and Crest Iliac before general anesthesia and under ultrasound after finding the extrinsic and intrinsic ablative muscles and the abdominal transducer needle muscle entered the skin along the probe and 20 cc bupivacaine 0.25% injection this site and in the control group, we injected 20 cc normal saline into the petit triangle between the abdominal intrinsic muscle and the transducer abdominis muscle

Main outcome variables

Pain, mean of narcotic drug

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N135**

Registration date: **2020-03-06, 1398/12/16**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-06, 1398/12/16**

Update count: **0**

Registration date

2020-03-06, 1398/12/16

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-31, 1398/10/10

Expected recruitment end date

2020-12-30, 1399/10/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Transversus Abdominis Plane(TAP) Block on pain control after open Appendectomy in uncomplicated acute appendicitis

Public title

Effect of Transversus Abdominis Plane(TAP) Block on pain control after open Appendectomy in uncomplicated acute appendicitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Ages 18 to 65 years No underlying disease Surgery less than one hour No addiction Absence of connective tissue disease Absence of rheumatic disease Diagnosis of uncomplicated acute appendicitis

Exclusion criteria:

Patients with perforated appendicitis Ovarian cyst rupture Tubo ovarian abscess

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with randomization with envelopes in two groups A and B . In this method, we selected a number of cards or letters as an intervention group and the same number of cards for the control group, then the cards were merged. One card was taken out and its allocation was registered and the card was returned to the other cards after leaving. Then the cards are merged again and we remove another card. This process continues to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer are blind (double blind). Outcome assessor and analyzer don't aware from grouping. The person evaluating the outcome is unaware of the grouping. Groups A and B are available to analyzer and outcome assessor.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Ethics committee, Research center, Payambar Azam complex, Basij square ,Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-12-29, 1398/10/08

Ethics committee reference number

IR.ARAKMU.REC.1398.271

Health conditions studied

1

Description of health condition studied

Appendicitis

ICD-10 code

K35

ICD-10 code description

Acute appendicitis

Primary outcomes

1

Description

Pain

Timepoint

In recovery and 2, 4, 6, 12, 24 and 48 hours after open appendectomy

Method of measurement

Visual analogue pain questionnaire

2

Description

mean of narcotic drug

Timepoint

24 hours after surgery

Method of measurement

Milligram

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group, we place the probe in the abdominal wall on the mid-axillary line between the lower ribs and Crest Iliac before general anesthesia and under ultrasound after finding the extrinsic and intrinsic ablative muscles and the abdominal transducer needle muscle entered the skin along the probe and 20 cc bupivacaine 0.25% injection this site

Category

Treatment - Drugs

2

Description

Control group: In the control group, we injected 20 cc normal saline into the petit triangle between the abdominal intrinsic muscle and the transducer abdominalis muscle

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Amirreza Naeemi

Street address

Valiasr square, Valiasr hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

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

Arak 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

Arak University of Medical Sciences

Full name of responsible person

Dr Siamak Rakei

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

General Surgery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr Amirreza Naeemi

Position

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Latest degree
Specialist
Other areas of specialty/work
General Surgery
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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Majid Javadi
Position
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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is 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

When we publish article in journal

When the data will become available and for how long

After the article is published

To whom data/document is available

Researcher in university

Under which criteria data/document could be used

If there are additional questions

From where data/document is obtainable

Dr Amirreza Naeemi

What processes are involved for a request to access data/document

They have to write letters to the professors and the university

Comments