

Clinical Trial Protocol

Iranian Registry of Clinical Trials

13 Jul 2026

Comparative study of the effect of TAP (Transverse Abdominis Plane) block and anesthesia infiltration site on postoperative pain in patients with unilateral inguinal hernia repair surgery

Protocol summary

Study aim

Comparison of Transverse Abdominis Plane block and local infiltration on postoperative pain in patients undergoing unilateral inguinal hernia repair surgery in Shahid Beheshti Hospital in Kashan in 2021

Design

In this randomized interventional one-side blinded IRCT, patients with unilateral inguinal hernia with the age of 18-70 years who are admitted to Shahid Beheshti Hospital to perform inguinal hernia repair in 2021 are included. Randomization will be done by picking a paper by an operation technologist via close eyes. After the termination of the surgery and before wakening the patient up one of the below interventions for the post operative pain management will be done. Transverse Abdominis Plane block or local anesthetics infiltration or no intervention.

Settings and conduct

Patients with unilateral inguinal hernia with the age of 18-70 years who refer to Shahid Beheshti Hospital in Kashan in 1400 to perform inguinal hernia repair will be included in the study. after the end of the operation for the postoperative pain management one of the below interventions will be done , Transverse Abdominis Plane block , local infiltration or no intervention for the control group

Participants/Inclusion and exclusion criteria

Patients with unilateral inguinal hernia with the age of 18-70 years who refer to Shahid Beheshti Hospital in Kashan in 1400. • No history of drug addiction • Patients with ASA grade one and two Do not take any pain medications 24 hours before surgery No history of allergy to bupivacaine • Complete informed consent

Intervention groups

group1, using 20 cc of bupivacaine 0.25% for the anesthesia Group 2, transabdominal anesthesia between the the abdominal muscles via ultrasound technique.

Injection of 20 cc bupivacaine 0.25% Group3, not each of above interventions

Main outcome variables

Pain severity score nausea and vomiting Opioid use 24 hours after surgery Intervention group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191103045320N2**

Registration date: **2022-12-21, 1401/09/30**

Registration timing: **retrospective**

Last update: **2022-12-21, 1401/09/30**

Update count: **0**

Registration date

2022-12-21, 1401/09/30

Registrant information

Name

Mohammad Shabani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-11, 1400/11/22

Expected recruitment end date

2022-08-27, 1401/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of the effect of TAP (Transverse Abdominis Plane) block and anesthesia infiltration site on postoperative pain in patients with unilateral inguinal hernia repair surgery

Public title

Comparative study of the effect of TAP (Transverse Abdominis Plane) block and anesthesia infiltration site on postoperative pain in patients with unilateral inguinal hernia repair surgery

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

No history of drug addiction Patients with ASA grade one and two Do not take any pain medications 24 hours before surgery
عدم سابقه حساسیت به بوی واکاژین Complete informed consent

Exclusion criteria:**Age**

From **18 years** old to **70 years** old

Gender

Both

Phase

0

Groups that have been masked

No information

Sample size

Target sample size: **63**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random method Randomization will be done by picking a piece of paper inside a glass by an operating room technologist with closed eyes , on the one third of the papers it is written that "Transverse Abdominis Plane block" and on the other one third it is written "local infiltration" , and on the rest of the one third it is written "control"

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of the Kashan University of Medical Sciences

Street address

Qutb Ravandi Boulevard

City

Kashan

Province

Isfahan

Postal code

8715973474

Approval date

2021-10-27, 1400/08/05

Ethics committee reference number

IR.KAUMS.REC.1400.046

Health conditions studied**1****Description of health condition studied**

Postoperative pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

Primary outcomes**1****Description**

Score of severity of the post operation pain

Timepoint

Before surgery, after admission to the recovery ward, 15 minutes after staying in the recovery ward, after admission to the surgery ward

Method of measurement

Pain is a subjective outcome, so, we ask the patients about the pain and they will score from 1 to 10 (10 = most severe). Other indicators of the pain such as hypertension, tachycardia, ECG changes, sweating, lacrimation and mydriasis will be considered.

2**Description**

Nausea and vomiting in the post operative period setting

Timepoint

Before surgery, after admission to the recovery ward, 15 minutes after staying in the recovery ward, after admission to the surgery ward

Method of measurement

Asking from the patient, observing patient situation

3

Description

Opioid consumption in the 24 hours after operation

Timepoint

Before surgery, after admission to the recovery ward, 15 minutes after staying in the recovery ward, after admission to the surgery ward

Method of measurement

Recording of the total opioid consumption in the patient document and in a piece of paper near the head of the patient

Secondary outcomes

1

Description

Postoperative pain (visceral pain)

Timepoint

Two, four, six, twelve and twenty-four hours after surgery

Method of measurement

Visual analog scale

Intervention groups

1

Description

Intervention group: TAP (transverse abdominis plane) Block Group, in this group local anesthetic (20 cc Bupivacaine .25 percent) will be injected in the transverse abdominis plane which is the site of the passage of the C fibers of the pain via ultrasound technique

Category

Treatment - Other

2

Description

Intervention group: Local anesthesia infiltration , in this group of the intervention local anesthetic (20 cc Bupivacaine .25 percent) will be injected in the surrounding site of the surgery wound

Category

Treatment - Other

3

Description

Control group: No intervention method, such as the classic and routine method, in this group no intervention in the operating room setting for the control of the post operative pain will be done.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Kashan Beheshti Hospital

Full name of responsible person

Dr. Mehdi Rajabi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

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Web page address

<http://research.kaums.ac.ir/Default.aspx?PageID=58>

Grant name

Grant code / Reference number

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

No

Title of funding source

Deputy of research and technology

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
Kashan University of Medical Sciences
Full name of responsible person
Mehdi Rajabi
Position
Pain anesthesiologist pain fellow
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Person responsible for updating data

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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

The data obtained from the comparison of the two methods of TAP block and infiltration in patients in comparison with the control group will be presented in the form of published text.

When the data will become available and for how long

After the implementation of the plan

To whom data/document is available

Vice Chancellor for University Research and researchers and project consultants.

Under which criteria data/document could be used

The data is usable and valuable in any outcome.

From where data/document is obtainable

Vice Chancellor for Research and Technology of Kashan University of Medical Sciences.

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

Necessary coordination should be provided in the Research Council of Kashan University of Medical Sciences according to the approved laws.

Comments