

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Comparison of efficacy of transversus abdominis plane block and iliohypogastric/ilioinguinal ultrasonic block for postoperative pain management in pediatric patients

Protocol summary

Study aim

Comparison of the efficacy of transverse abdominal muscle block with ileohypogastric / ileoinguinal block using ultrasound in postoperative pain management

Design

Clinical trial with control group, with parallel group design, triple blind, randomized with 50 subjects

Settings and conduct

This study will be performed on children in need of inguinal hernia repaired on Tabriz Children Hospital Operating Room and only the hospital operating room will be informed of the groupings. The statistical analyzer is also unaware of the block method and derived sequence and therefore the study will be a triple blind. The study will be designed and conducted based on the descriptions given in the description of how to become blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria; 6-12 year-old children; Children with ASA Class I and II require inguinal hernia repair; exclusion criteria; parental dissatisfaction with regional block; and allergy to topical anesthesia.

Intervention groups

Intervention group: Children who will undergo ultrasound guided transverse abdominal muscle block for surgery, In the intervention group, the needle was inserted medial to lateral fashion and after reaching the tip of the needle to the fascia between the IO and TA muscles 0.2ml / kg of 0.25% bupivacaine solution (ie 0.5mg / kg) are injected around the nerves. Control group: Children will undergo ultrasonic guided iliohypogastric / ileoinguinal block.

Main outcome variables

The amount of pain; The amount of used analgesic drug; The time it takes to do blocking; The time that patient need the first analgesic drug.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190730044383N1**

Registration date: **2020-02-18, 1398/11/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-18, 1398/11/29**

Update count: **0**

Registration date

2020-02-18, 1398/11/29

Registrant information

Name

Arefe Khanoghan

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-18, 1398/06/27

Expected recruitment end date

2020-09-17, 1399/06/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of transversus abdominis plane block and iliohypogastric/ilioinguinal ultrasonic block for postoperative pain management in pediatric patients

Public title

Comparison of efficacy of different nerve block with ultrasonic guide for postoperative pediatric pain management

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Children aged 6-12 years old Children with ASA Class I and II requiring inguinal hernia repair

Exclusion criteria:

Parental dissatisfaction with performing regional block Allergy to local anesthesia will be

Age

From **6 years** old to **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be a layer randomization such that depending on patient ID , if the ID is an even number, ultrasound guidance TAP block will be conducted for him/her and if it is odds number, the ultrasound guidance IIN / IHN block will be done.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The head of the operating room of the Tabriz Pediatric Hospital will be aware of this. During surgery and after recovery, the examiner will examine the patient and record the relevant criteria for the patient without knowing which treatment method is selected. The statistical analyzer is also unaware of the block method and therefore will be a triple blind study. The surgery was the same in both groups but the analgesic method differed in both groups. depending on patient ID , if the ID is an even number, ultrasound guidance TAP block will be conducted for him/her and if it is odds number, the ultrasound guidance IIN / IHN block will be done. And since the anesthesiologist will proceed with the procedure according to the file number, so he or she will not be aware of the child's grouping, so the parents of the child are also unaware of the type of block.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Tabriz Medical School

Street address

Imam Reza Hospital, Golghast street, Azadi street, Tabriz

City

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Province

East Azarbaijan

Postal code

5166614756

Approval date

2019-07-30, 1398/05/08

Ethics committee reference number

IR.TBZMED.REC.1398.468

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

Comparison of the efficacy of abdominal transverse muscle block with ileohypogastric / ileoengyngal block

ICD-10 code

ندارد

ICD-10 code description

ندارد

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

The amount of pain

Timepoint

6 to 12 months after surgery

Method of measurement

visual analogue scale

2**Description**

The amount of used analgesic drug

Timepoint

recovery period

Method of measurement

Questionnaire

3

Description

The time it takes to do the block

Timepoint

during the procedure

Method of measurement

Questionnaire

4

Description

The time that patient needs the first analgesic drug

Timepoint

during recovery

Method of measurement

Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: in this group ultrasound probe is placed transversely in midaxillary line, between iliac crest and inferior rib margins. After ultrasonographic view of abdominal wall layer is obtained, Needle gauge of 20 or 22 (according to the child's age) is inserted medial to the lateral plane and after reaching the needle tip to the fascia between the IO and TA muscles 0.4ml / kg of 0.25% bupivacaine solution (ie 1mg) / kg will be injected. In case of bilateral inguinal hernia repair (or surgical incision beyond the midline of the body), in each case, the above-mentioned area blocks will be bilateral. In all of the above, the dose of topical anesthesia drugs should not exceed toxic dosage (2mg / kg bupivacaine)

Category

Treatment - Surgery

2

Description

Control group: In this group the ultrasound probe is placed transversely in center of imaginary line between anterior superior iliac spine and navel and the lateral end of the probe adheres to the anterior superior iliac spine. Needle gauge of 20 or 22 (according to child's age) is in-plane medially lateral to body and after needle tip reached to fascia between IO and TA muscles 0.2ml / kg of 0.25% bupivacaine solution (ie 0.5 mg / kg) will be injected in the vicinity of the above nerves and a "Kayak" view or mark will be obtained.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Tabriz 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

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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