

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the analgesic effect of ultrasound-guided posterior quadratus lumborum block and ultrasound-guided ilioinguinal/iliohypogastric nerve block for pediatric lower abdominal surgery: A Prospective, randomized double-blinded study

Protocol summary

Study aim

Comparison of the analgesic effect of ultrasound-guided posterior quadratus lumborum block and ultrasound-guided ilioinguinal/iliohypogastric nerve block for pediatric lower abdominal surgery

Design

Clinical trial with parallel groups, double-blind, randomized, phase 3 on 60 children candidates for lower abdominal surgeries, computer software will be used for randomization.

Settings and conduct

This study is conducted in Ali Asghar Children's Hospital. Eligible children and candidates for inguinal hernia surgery and orchiopexy are randomly assigned to 2 groups. After induction of anesthesia in group 1 quadratus lumborum block and in group 2 ilioinguinal/iliohypogastric block both will be performed under ultrasound guidance. In this study, children do not know the type of treatment method.

Participants/Inclusion and exclusion criteria

Entry criteria included: Candidate patients for unilateral inguinal hernia surgery and unilateral orchiopexy in the age range of 4 to 12 years, and Having informed consent from parents, ; Exclusion criteria include a history of surgery in the block area, Coagulation disorder, ASA class three and above, drug use before surgery, sensitivity to local anesthetics, infection or redness at the injection site, liver, kidney and heart diseases and children with cerebral palsy.

Intervention groups

In group 1, or Quadratus Lumborum group: First, to confirm the correct location of the needle tip, 0.5cc of normal saline is injected And then 0.5cc/kg of ropivacaine 0.2% will be injected after negative aspiration. In group 2, or ilioinguinal/iliohypogastric group :First 0.5cc of normal saline will be injected to confirm

the correct location And after confirming the location and performing negative aspiration, 0.2cc/kg ropivacaine 0.2% will be slowly injected around the nerve.

Main outcome variables

Pain score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230506058100N2**

Registration date: **2023-09-16, 1402/06/25**

Registration timing: **prospective**

Last update: **2023-09-16, 1402/06/25**

Update count: **0**

Registration date

2023-09-16, 1402/06/25

Registrant information

Name

Tahereh Chavoshi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2304 6253

Email address

chavoshi.t@iums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-10-23, 1402/08/01

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the analgesic effect of ultrasound-guided posterior quadratus lumborum block and ultrasound-guided ilioinguinal/iliohypogastric nerve block for pediatric lower abdominal surgery: A Prospective, randomized double-blinded study

Public title

Comparison of the analgesia effect of two types of abdominal block in children candidates for lower abdominal surgeries

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Candidate patients for unilateral inguinal hernia surgery and unilateral orchiopexy In the age range of 4 to 12 years Having informed consent from parents

Exclusion criteria:

History of surgery in the block area Coagulation disorder ASA class three and above Opium use before surgery Sensitivity to local anesthetics Infection or redness at the injection site Liver, kidney and heart diseases Children with cerebral palsy

Age

From **4 years** old to **12 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, simple and individual randomization method is used. The Sealed Envelope site is used to generate random sequences. The website address is <https://www.sealedenvelope.com>. Each of the generated random sequences contains a unique code for hiding. First, using a computer program, such as Microsoft Excel or SAS, a sequence of random numbers will be generated. Then, based on the randomization sequence, the participants will be assigned to 2 quadratus lumborum block groups and ilioinguinal/iliohypogastric block groups, and by using sealed envelopes, this allocation will be hidden, and the participants will be assigned to the appropriate groups according to the order of allocation.

Blinding (investigator's opinion)

Double blinded

Blinding description

Blinding the patient: due to their condition and being unconscious, the patients are unaware of the treatment process and the patient's companion does not know which method was used for the disease. Blinding of the outcome assessor: Data collectors will not be aware of the type of block and management during surgery and postoperative evaluation and will record all hemodynamic items, questionnaire interventions, and postoperative evaluations.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

کمیته اخلاق دانشگاه علوم پزشکی ایران

Street address

Iran University of Medical Sciences, Next to Milad Tower; Shahid Hemat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2023-08-21, 1402/05/30

Ethics committee reference number

IR.IUMS.REC.1402.475

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

pediatric candidates for lower abdominal surgeries

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Pain score

Timepoint

30 minutes after transferring to the recovery room and 1, 2, 4, 6, 12, 24 hours after the operation

Method of measurement

Number based on Falcc Score

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In group 1 or quadratus lumborum group, where the posterior approach is selected, the patient will be lateralized and the side that is not operated on will be placed on the bed. The ultrasound probe will be placed in the midaxillary line between the rib edge and the iliac crest. After identifying the three layers of abdominal muscles, the probe is guided posteriorly until the external oblique and internal oblique muscles reach the quadratus lumborum muscle. Then, needle number 22 is inserted with in-plane approach from front to back. The goal of the needle tip is to reach between the quadratus lumborum muscle and the erector spinae muscle, where the middle part of the thoracolumbar fascia reaches the posterior surface of the quadratus lumborum muscle. First, to confirm the correct location of the needle tip, 0.5cc of normal saline will be injected, and then 0.5cc/kg of ropivacaine 0.2% will be injected after negative aspiration.

Category

Treatment - Surgery

2

Description

Intervention group: In group 2 or ilioinguinal/iliohypogastric block group, in the supine position, we will place the ultrasound probe above the superior anterior sphincter, in alignment with the space between the navel and the superior anterior sphincter, so that three layers of muscle can be seen clearly. Then we find the ilioinguinal/iliohypogastric nerves in the form of two hypoechoic structures between the internal oblique muscle and the transverse abdominis and after preparation and drape and under sterile conditions, we insert the needle from the medial to the lateral side with an in-plane approach and near the nerves, first 0.5cc of normal saline will be injected to confirm the correct location, and after confirming the location and performing negative aspiration, 0.2cc/kg of ropivacaine 0.2% will be slowly injected around the nerve.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Asghar Children's Hospital

Full name of responsible person

Tahereh Chavoshi

Street address

No.193, Zafar street, Modares Highway

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6252

Email

chavoshi.t@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Reza Falak

Street address

Next to Milad Tower; Shahid Hemat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 2503

Email

falak.r@iums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Tahereh Chavoshi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No.193, Zafar st, Modares Highway

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6252

Fax

Email

chavoshi.t@iums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Tahereh Chavoshi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No. 193, Zafar st, Moddares Highway

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6252

Email

Chavoshi.t@iums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Tahereh Chavoshi

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

No. 193, Zafar st, Moddares Highway

City

Tehran

Province

Tehran

Postal code

1919816766

Phone

+98 21 2304 6252

Email

Chavoshi.t@iums.ac.ir

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

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable