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/iliohipogastric 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 Lumbarum 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)

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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/iliohipogaster 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 lumbarum 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 intertal 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 spinea 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

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No.193, Zafar street, Modares Highway

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran 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
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

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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

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