Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

The success rate and complication of caudal block and spinal anesthesia for awake preterm infants undergoing inguinal repair

Protocol summary

Summary

Written informed parental consent in a double blind randomized clinical trial, 66 infants (ASA I or II), undergoing inguinal hernia repair will be recruited in Tabriz Teaching Children Hospital during a 12-month period of time. We explained these two forms of regional anesthesia and their complications to the parents throughout the preoperative visits. All patients were given IV midazolam (0.03 mg/kg) before performing block.. Monitoring included pulse oximetry, electrocardiogram, and non-invasive blood pressure monitoring and precordial stethoscope. A maintenance IV 5% dextrose in was infused from the start of preoperative fasting time (4 hours prior to the operation). In group C, infants were in left lateral position with flexion of hip. A 22-gauge caudal needle was selected to perform the block. After negative aspiration test, we injected 1ml/kg of 0.25% Bupivacaine, with 20µg adrenaline 1:1000 in caudal space, then the infant was turned into supine position.Successful caudal anesthesia was defined as lack of sensation to pinch at the desired sensory level and paralysis of lower limbs after 15 minutes. In group S, an assistant seated the infant on a folded towel 10 cm above the operative table. The head was placed in neuter positional 2.5cm, 25-gauge Quincke spinal needle was inserted into L5-S1interspace. This approach was adopted to avoid potential damage to the conus medullaris terminating at L3 in infants. Subarachnoid placement was confirmed by free flow of CSF. With the needle stabilized, the local anesthetic solution i.e. 1mg/kg of 0.5% hyperbaric Bupivacaine, with 20µg adrenaline 1:1000 was rapidly injected. The patient was immediately positioned supine with a 20-30° head up tilt for two to three minutes, and then horizontally. Successful spinal anesthesia was defined as lack of sensation to pinch at the desired sensory level and paralysis of lower limbs after 2 minutes. In all patients, we recorded vital signs (systolic and diastolic blood pressure, heart rate and SpO2) before induction, after 10, 20, and 30 minutes of block, at the end of surgery, at the beginning of the recovery, 10 and 20 minutes of the recovery phase, and at the end of the recovery. We also recorded presence of apnea and need for analgesia at the post-operation period up to 24 hour. NIPS was used to assess pain score; consisting of six criteria: facial expression, cry, breathing pattern, arms and legs positions, and state of arousal. In group c 25 min after block and in group s just after block the surgery started. In the case of unsuccessful block general anesthesia was induced. The aim of this study was to compare complication and success rates of caudal block and spinal anesthesia in awake preterm infants undergoing inguinal hernia repair

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201102014041N4**
Registration date: **2013-05-10, 1392/02/20**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2013-05-10, 1392/02/20

Registrant information

Name

Mahin Seyedhejazi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source
Tabriz University of Medical Sciences

Expected recruitment start date
2009-12-22, 1388/10/01

Expected recruitment end date
2011-01-21, 1389/11/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The success rate and complication of caudal block and spinal anesthesia for awake preterm infants undergoing inguinal repair

Public title
Caudal block & spinal block in neonate

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criterion: infants less than 5 kg candidate for inguinal hernia repair. Exclusion criteria: any contraindication to regional blocks in children; major malformation of the sacrum; meningitis and intracranial hypertension.

Age
To **1 year** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **66**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Tabriz University of Medical Sciences

Street address
Tabriz University of Medical Sciences

City
Tabriz

Postal code

Approval date
2009-11-16, 1388/08/25

Ethics committee reference number
8813

Health conditions studied

1

Description of health condition studied
Regional blocks in infants

ICD-10 code
K40.2

ICD-10 code description
Bilateral inguinal hernia, without obstruction or gangrene

Primary outcomes

1

Description
Pain

Timepoint
Two, 4, 6 and 8 hours postoperative

Method of measurement
Neonatal infant pain scale(NIPS)

Secondary outcomes

empty

Intervention groups

1

Description
In first group :caudal block by 1mg/kg of 0.25% bupivacaine plus 20µg adrenaline (group C)

Category
Prevention

2

Description
In second group: spinal block by 1mg/kg of 0.5% hyperbaric Bupivacaine, with 20µg adrenaline 1:1000 (group s)

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Children Hospital

Full name of responsible person

Dr.Mahin Seyedhejazi

Street address

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Alireza Ostadrahimi

Street address

Tabriz University of Medical Sciences-Golgasht Ave

City

Tabriz

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tabriz University Of Medical Sciences

Full name of responsible person

Dr. Mahin Seyedhejazi

Position

Associate Professor of Anesthesia

Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty