

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Dexmedetomidine sedation in awake caudal block for lower abdominal surgeries in neonates

Protocol summary

Study aim

Dexmedetomidine sedation in awake caudal block for lower abdominal surgeries in neonates

Design

Clinical trial with intervention groups, with parallel groups, double-blinded, randomized

Settings and conduct

In this double-blind randomized clinical trial, 100 patients Weighing less than 4 Kg from Tabriz children hospital with American society of Anesthesiologists (ASA) status I and II, undergoing lower abdominal surgeries will be enrolled The patients will be randomized in one of the two groups of Sedation with Dexmedetomidine (D) and sedation with Normal saline(N)

Participants/Inclusion and exclusion criteria

Inclusion criteria: Neonates Weighing less than 4 Kg
Surgery of the lower abdomen ASA Class I and II
Exclusion criteria: Patients with congenital neurological disease and seizures Caudal injection site infection
Sepsis Sensitivity to topical anesthetics
Bradycardia(HR<120) Any kind of heart block Congenital cyanotic heart diseases

Intervention groups

neonates first intervention group with ASA class I and II after proper monitoring including ECG and SPO2 NIBP in D group neonates Receive Dexmedetomidine 1ml/kg and N group infant receive normal saline 1ml/kg. after administration of the drug the patients vital signs are recorded and repeated every 1 minute and 3 minute after administration of the drug neonates in the lateral position with a 22G needle and bolupasaine 0/2%(1MG/KG) plus epinephrine 1-2 mg experiences are under the caudal block

Main outcome variables

Blood pressure.Heart rate.SPO2, duration of stay in recovery.Apene.number of times to do caudal block.duration of performance caudal block, Sedation Score

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190114042358N3**

Registration date: **2020-04-23, 1399/02/04**

Registration timing: **retrospective**

Last update: **2020-04-23, 1399/02/04**

Update count: **0**

Registration date

2020-04-23, 1399/02/04

Registrant information

Name

Daryoush Sheikhzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3526 2257

Email address

dr.d.sheik@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2020-01-21, 1398/11/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Dexmedetomidine sedation in awake caudal block for lower abdominal surgeries in neonates

Public title
Dexmedetomidine sedation in awake caudal block for lower abdominal surgeries in neonates

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Infant Weighing less than 4 Kg Surgery of the lower abdomen ASA Class 1 and 2
Exclusion criteria:
 Patients with congenital neurological disease and seizures Caudal injection site infection Sepsis Sensitivity to topical anesthetics Bradycardia(HR<120) Any kind of heart block Congenital cyanotic heart diseases

Age
From **1 day** old to **30 days** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **100**

Randomization (investigator's opinion)
Randomized

Randomization description
Random method: Block, Random unit: individual, Random Tool: Random Block 4. for this purpose, 25 blocks with 4 subjects in each block will be used. the combination of all patterns will be considered including AABB, ABAB, BABA, BBAA, BABA, BAAB. For selecting each blocks, dice dropped and the block number will be selected. this procedure continued to completed the allocation and reached to sample size.

Blinding (investigator's opinion)
Double blinded

Blinding description
This is a double-blinded study and Researcher and patients are kept unaware of intervention in each group and In order to allocation concealment, the type of intervention will be written on paper and placed in numbered, matte and packed envelopes. The envelopes will be opened in the order of participation of the participants and the type of group will be determined

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Tabriz University of Medical Science, Gholghasht, Azadi Street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5166616471

Approval date

2020-01-06, 1398/10/16

Ethics committee reference number

IR.TBZMED.REC.1398.10.92

Health conditions studied

1

Description of health condition studied

caudal block(Local anaesthetics)

ICD-10 code

Y48.3

ICD-10 code description

Anaesthetics and therapeutic gases

Primary outcomes

1

Description

Blood pressure

Timepoint

After entering the operating room. After doing caudal block every 1 minute to 5 minutes and every 5 minutes till release from recovery

Method of measurement

Monitor

2

Description

Heart rate

Timepoint

After entering the operating room. After doing caudal block every 1 minute to 5 minutes and every 5 minutes till release from recovery

Method of measurement

ECG device

3

Description

SPO2

Timepoint

After entering the operating room. After doing caudal block every 1 minute to 5 minutes and every 5 minutes till release from recovery

Method of measurement

pulse oximeter device

4

Description

Duration of the block

Timepoint

after proper monitoring in D group of neonates receive 1ml/kg Dexmedetomidine and in N group of neonates receive normal saline (1ml/kg) after administering the drug the time required to perform the caudal block is recorded

Method of measurement

by an experienced anesthesiologist

5

Description

the number of attempts for block

Timepoint

after proper monitoring in D group of neonates receive 1ml/kg Dexmedetomidine and in N group of neonates receive 1ml/kg normal saline after administering the drug the number of times you try to perform caudal block is recorded

Method of measurement

by an experienced anesthesiologist

6

Description

Duration of stay in recovery

Timepoint

After entering till release from recovery

Method of measurement

According to Alderet Score

7

Description

Apnea

Timepoint

After entering till release from recovery

Method of measurement

monitor and face and color scale

8

Description

Sedation

Timepoint

15 minutes after the block, and then every 5 minutes till release from recovery

Method of measurement

Sedation score table

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: neonates first intervention group with ASA class I and II after proper monitoring including ECG and SPO2 NIBP in D group neonates receive Dexmedetomidine 1ml/kg after administration of the drug the patients vital signs are recorded and repeated every 1 minute and 3 minute after administration of the drug neonates in the lateral position with a 22G needle and bolupasaine 0/2% (1MG/KG) plus epinephrine 1-2 mg experiences are under the caudal block

Category

Treatment - Drugs

2

Description

Intervention group: neonates first intervention group with ASA class I and II after proper monitoring including ECG and SPO2 NIBP in N group infant receive normal saline 1ml/kg. after administration of the drug the patients vital signs are recorded and repeated every 1 minute and 3 minute after administration of the drug neonates in the lateral position with a 22G needle and bolupasaine 0/2% (1MG/KG) plus epinephrine 1-2 mg experiences are under the caudal block

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Tabriz Childrens Hospital

Full name of responsible person

Daryoush Sheikhzadeh

Street address

Tabriz Childrens Hospital, Sheshgelan St

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3526 2255

Email

dr.d.sheik@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Tabriz University of Medical Sciences, Golghasht St

City

Tabriz

Province

East Azarbaijan

Postal code

5136735886

Phone

+98 41 3335 7310

Email

ajouyban@hotmail.com

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

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Daryoush Sheikhzadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Tabriz Childrens Hospital, Sheshgelan St

City

Tabriz

Province

East Azarbaijan

Postal code

5136735883

Phone

+98 41 3526 2255

Email

dr.d.sheik@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Daryoush Sheikhzadeh

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Tabriz Childrens Hospital, Sheshgelan St

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Phone

+98 41 3526 2255

Email

dr.d.sheik@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Daryoush Sheikhzadeh

Position

Assistant Professor

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

No - There is not 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

Undecided - It is not yet known if there will be a plan to make this available	All Physicians and residents of the department of Anesthesia
Data Dictionary	Under which criteria data/document could be used
Undecided - It is not yet known if there will be a plan to make this available	After obtaining permission from the deputy research of group
Title and more details about the data/document	From where data/document is obtainable
A portion of the data that represents the final outcome	Person responsible for scientific accountability of study
When the data will become available and for how long	What processes are involved for a request to access data/document
Access will be 6 months after the results are printed.	First approved by the Research Vice-President
To whom data/document is available	Comments