Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Jun 2026

Efficacy of dexmedetomidine as an adjuvanct to ropivacaine in pediatric caudal epidural block

Protocol summary

Study aim

The aim of current study is to evaluate the efficacy of dexmedetomidine in adjunct to ropivacaine compared to ropivacaine alone before extubation in pediatric caudal epidural block.

Design

In this research, 46 patients undergoing lower abdomen surgeries with inclusion criteria and not having exclusion criteria r will be included. Patients will be randomly allocated to ropivacaine alone or in adjunct to dexmedetomidine groups and each patient will be given a specific code.

Settings and conduct

After patients selection, they will be randomly allocated to ropivacaine alone or in adjunct to dexmedetomidine groups. Pain severity (using Modified Children's Hospital of Eastern Ontario Pain Scale) after 1, 2 and till 6 hours post surgery, the amount and type of analgesics used, recovery duration and possible side effects will be evaluated in both groups. Patients' parents and the person evaluating the treatment outcome will be unaware of the allocated groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age 3-10 years, ASA class I or II, Lower abdomen and below epigastric surgeries including hernia and UDT, surgery period 30 minutes to 2 hours, no sensitivity to ropivacaine and dexmedetomidine.
Exclusion criteria: complicated surgeries (long or bleeding in need of transfusion), Parents do not agree for children to participate.

Intervention groups

After randomization, before extubation one group will receive ropivacaine 0.2% 1.5 mg/kg alone and other group will receive ropivacaine 0.2% 1.5 mg/kg with dexmedetomidine 1 microgram per kg.

Main outcome variables

The main outcome of the study is pain severity using Modified Children's Hospital of Eastern Ontario Pain Scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20111102007984N30**
Registration date: **2019-10-05, 1398/07/13**
Registration timing: **registered_while_recruiting**

Last update: **2019-10-05, 1398/07/13**
Update count: **0**

Registration date

2019-10-05, 1398/07/13

Registrant information

Name
Farnad Imani
Name of organization / entity
Iran University of Medical Sciences
Country
Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-21, 1397/09/30

Expected recruitment end date

2019-12-21, 1398/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Efficacy of dexmedetomidine as an adjuvanct to ropivacaine in pediatric caudal epidural block

Public title
Efficacy of dexmedetomidine as an adjuvanct to ropivacaine in pediatric caudal epidural block

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
ASA class I or II Lower abdomen and epigastric surgeries like hernia and UDT Surgery time between 30 minutes and 2 hours No sensitivity to dexmedetomidine and ropivacaine

Exclusion criteria:
Complicated surgeries (long or bleeding in need of transfusion) Parents do not give consent for their children to participate

Age
From **3 years** old to **10 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **46**

Randomization (investigator's opinion)
Randomized

Randomization description
By using the randomize number table, the patients were divided into two equal groups (n=23).

Blinding (investigator's opinion)
Double blinded

Blinding description
Both drugs are injectable and the injection site of both drugs in the patients' body is in the same area. Therefore, patients' parents are not aware of the type of drug. Also, the outcome evaluator is unaware of the random allocation.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Expressway corner

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2018-12-09, 1397/09/18

Ethics committee reference number
IR.IUMS.FMD.REC.1398.077

Health conditions studied

1

Description of health condition studied
Postoperative pain

ICD-10 code
G89.18

ICD-10 code description
Other acute postprocedural pain

Primary outcomes

1

Description
Postoperative pain

Timepoint
One, two and till 6 hours after surgery

Method of measurement
Using Modified Children’s Hospital of Eastern Ontario Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: First group will receive ropivacaine 0.2%, 1.5 mg/kg (maximum 25 mg) before extubation.

Category
Treatment - Drugs

2

Description
Intervention group: The second group will receive ropivacaine 0.2%, 1.5 mg/kg (maximum 25 mg) in adjunct to dexmedetomedine 1 microgram per kg before extubation.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Hazrat- Rasul Akram Medical Coplex

Full name of responsible person
Farnad Imani

Street address
Anesthesiology and pain department of Hazrat-Rasoul Medical Complex, Niayesh street, Sattar-Khan street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Seyed Kazem Malakoti

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Iran University of Medical Sciences, Hemmat highway

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research@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
Farnad Imani

Position
Interventional pain fellowship, professor of anesthesiology

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Pain Research Center, Department of Anesthesiology and Pain Medicine, Rasool Akram Medical Center, Niayesh St. Sattar Khan St

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available

Study Protocol
Yes - There is 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

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

Title and more details about the data/document
Some part of the clinical information of the patients will be shared

When the data will become available and for how long
6 months after the end of the project

To whom data/document is available
Faculty Members of Medical Sciences Universities

Under which criteria data/document could be used
For further studies

From where data/document is obtainable
Deputy of Research & Technology Pain Research Center, Iran University of Medical Sciences

What processes are involved for a request to access data/document
First, at the request of the university, she/he will be informed at the request of the university's deputy of the research department, and then she/he will be referred to the research center during the administrative process and the data will be received by the committee of the research center of the center with a commitment and acceptance.

Comments