Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

comparison of adding dexmedetomidine and tramadol and neostigmine to lidocaine 1.5% for reduce postoprative pain in caudal block in 2-8 children lower abdominal surgeries

Protocol summary

Study aim

Aim of this study is comparison of adding dexmedetomidine and tramadol and neostigmine to lidocaine 1.5% for reduce postoperative pain in caudal block in 2-8 children lower abdominal surgeries.

Design

This study is clinical trial. 96 children enllore the study under lower abdominal surgery.We will divide patients in 3 groups(Dexmedetomidine, Tramadol and Neostigmine).

Settings and conduct

This study is clinical trial. This study is double blinde.96 children enllore the study under lower abdominal surgery. This study is double blind.Outcome elevator and analyzer are blind (double blind).Outcome elevator and analyzer don't aware from grouping.We will divide patients in 3 groups(Dexmedetomidine, Tramadol and Neostigmine).

Participants/Inclusion and exclusion criteria

Inclusion criteria:Children 8-2 years old, ASA class I and II, all patients without heart disease, pulmonary, liver, patients without seizure history, patients who duration of operation is between 45- 90 minutes, local anesthetics, dexmedetomidine, tramadol and neostigmine Exclusion criteria:All patients with a duration of more than 90 minutes, all patients with failure in codal block

Intervention groups

We will divide patients in 3 groups(Dexmedetomidine, Tramadol and Neostigmine).We inject 1 micro gram in kilogram Dexmedetomidine(1 milliliter) as adjutant Lidocain in Dexmedetomidine group.We inject 1 milliliter in kilogram Tramadol (1 milliliter) as adjutant Lidocain in Tramadol group.We inject 1.5 micro gram in kilogram Neostigmine (1 milliliter) as adjutant Lidocain in Neostigmine group.

Main outcome variables

Mean narcotic drug during the 24 first after surgery - duration of analgesia-pain in recovery, 2, 6 and 12 hours after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N83**
Registration date: **2018-08-29, 1397/06/07**
Registration timing: **registered_while_recruiting**

Last update: **2018-08-29, 1397/06/07**
Update count: **0**

Registration date

2018-08-29, 1397/06/07

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 86 3222 2003

Email address

f.farokhi@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-10-08, 1396/07/16

Expected recruitment end date

2019-10-08, 1398/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

comparison of adding dexmedetomidine and tramadol and neostigmine to lidocaine 1.5% for reduce postoprative pain in caudal block in 2-8 children lower abdominal surgeries

Public title

comparison of adding dexmedetomidine and tramadol and neostigmine to lidocaine 1.5% for reduce postoprative pain in caudal block in 2-8 children lower abdominal surgeries

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children 8-2 years old ASA class I and II All patients without heart disease, pulmonary, liver and ... Patients without seizure history Patients who duration of operation is between 45- 90 minutes Local anesthetics, dimethomidine, tramadol and neostigmine

Exclusion criteria:

All patients with a duration of more than 90 minutes. All patients with failure in codal block

Age

From **2 years** old to **8 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size

Target sample size: **96**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple randomization with random numbers

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind.Outcome elevator and analyzer are blind (double blind).Outcome elevator and analyzer don't aware from grouping.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee Of Arak University Of Medical Sciences

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

848176941

Approval date

2017-10-08, 1396/07/16

Ethics committee reference number

IR.ARAKMU.REC.1396.112

Health conditions studied

1

Description of health condition studied

caudal block

ICD-10 code

T41.3

ICD-10 code description

Local anaesthetics

Primary outcomes

1

Description

Mean narcotic drug

Timepoint

24 hours first after surgery

Method of measurement

milligram

2

Description

duration of analgesia

Timepoint

24 hours first after surgery

Method of measurement

minute

3

Description

Pain

Timepoint

recovery, 2, 6 and 12 hours after surgery

Method of measurement

Visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: We inject 1 micro gram in kilogram Dexmedetomidine(1 milliliter) as adjutant Lidocain in Dexmedetomidine group.
Category
Treatment - Drugs

2

Description
Intervention group: We inject 1 milliliter in kilogram Tramadol (1 milliliter) as adjutant Lidocain in Tramadol group.
Category
Treatment - Drugs

3

Description
Intervention group: We inject 1.5 micro gram in kilogram Neostigmine (1 milliliter) as adjutant Lidocain in Neostigmine group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Valiasr Hospital
Full name of responsible person
Dr Alireza Kamali
Street address
Valiasr Hospital, Arak
City
Arak
Province
Markazi
Postal code
848176941
Phone
+98 86 3222 2003
Email
alikamaliir@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Mohammad Arjmandzadegan
Street address
Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
848176941
Phone
+98 86 3222 2003
Email
alikamaliir@yahoo.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Arak 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
Arak University of Medical Sciences
Full name of responsible person
Dr Bijan Yazdi
Position
Faculty, Anesthesiologist
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Valiasr Hospital, Valiasr squre, Shahid Shirodi street
City
Arak
Province
Markazi
Postal code
3814957558
Phone
+98 86 3222 2003
Fax
+98 86 3222 2003
Email
Yazdi@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Alireza Kamali
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
Amiralmomenin Hospital, Sardasht
City
Arak
Province
Markazi
Postal code
848176941
Phone
+98 86 3417 3614
Fax
Email
alikamaliir@yahoo.com
Web page address

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Tara Hasani Godarzi
Position
medicine student
Latest degree
A Level or less
Other areas of specialty/work
General Practitioner
Street address
Payambar Azam Complex, Basij square, Sardasht, Arak
City
Arak
Province
Markazi
Postal code
848176941
Phone
+98 86 3222 2003
Email
tara_hasanii@yahoo.com

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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
When we publish article in journal
When the data will become available and for how long
After the article is published
To whom data/document is available
researcher in university
Under which criteria data/document could be used
If there are additional questions
From where data/document is obtainable
Dr Alireza Kamali
What processes are involved for a request to access data/document
They have to write letters to the professors and the university
Comments