

Clinical Trial Protocol

Iranian Registry of Clinical Trials

12 Jun 2026

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

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 enroll 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 blind. 96 children enroll the study under lower abdominal surgery. This study is double blind. Outcome evaluator and analyzer are blind (double blind). Outcome evaluator 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 caudal 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 adjunct Lidocaine in Dexmedetomidine group. We inject 1 milliliter in kilogram Tramadol (1 milliliter) as adjunct Lidocaine in Tramadol group. We inject 1.5 micro gram in kilogram Neostigmine (1 milliliter) as adjunct Lidocaine 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 postoperative 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 postoperative 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

alikalaliir@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

alikalaliir@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 square, 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**

alikalaliir@yahoo.com

Web page address

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

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,