

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Efficacy of tramadol as an adjuvant to ropivacaine in pediatric caudal epidural block

#### Protocol summary

##### Study aim

The aim of current study is to evaluate the efficacy of tramadol added to ropivacaine compared to ropivacaine alone in caudal epidural block in children

##### Design

In this research, 46 children 3-10 years old undergoing lower abdomen surgeries with inclusion criteria and not having exclusion criteria will be included. Patients will be randomly allocated to ropivacaine alone or in combination with tramadol 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 combination with tramadol groups. The pain severity (using Modified Children's Hospital of Eastern Ontario Pain Scale) after 1, 2 and 6 hours post surgery, type and dose of analgesics used and recovery time as well as possible side effects will be evaluated in each group. Patients' parents and the person evaluating the treatment outcome will be blinded to the allocated groups.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: American Society of Anesthesiologists class I and II, Surgery duration 30 minutes to 2 hours, No sensitivity to tramadol and ropivacaine. Exclusion criteria: Complicated surgeries (long or bleeding in need of transfusion), Parent do not consent for their child to participate

##### Intervention groups

After randomization, patients will receive ropivacaine 0.2% with proper dose per Kg alone or in combination with tramadol 2 mg /kg before extubation.

##### Main outcome variables

The main outcome variable will be pain severity using Modified Children's Hospital of Eastern Ontario Pain Scale

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190929044924N1**  
Registration date: **2019-11-10, 1398/08/19**  
Registration timing: **retrospective**

Last update: **2019-11-10, 1398/08/19**

Update count: **0**

##### Registration date

2019-11-10, 1398/08/19

##### Registrant information

##### Name

Reza Farahmandrad

##### Name of organization / entity

Iran University Of Medical Science

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 8852 2083

##### Email address

farahmandrad.r@iums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2018-11-22, 1397/09/01

##### Expected recruitment end date

2019-10-23, 1398/08/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Efficacy of tramadol as an adjuvant to ropivacaine in pediatric caudal epidural block

**Public title**

Effect of tramadol as an adjuvant to ropivacaine in pediatric caudal epidural block

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

American Society of Anesthesiologists (ASA) class I and II  
Surgery duration 30 minutes to 2 hours  
No sensitivity to tramadol and ropivacaine

**Exclusion criteria:**

Complicated surgeries (long or bleeding in need of transfusion)  
Parent do not consent for their child 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 high way

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Approval date**

2018-10-23, 1397/08/01

**Ethics committee reference number**

IR.IUMS.FMD.REC.1398.107

**Health conditions studied****1****Description of health condition studied**

pain control

**ICD-10 code**

G89.18

**ICD-10 code description**

Other acute postprocedural pain

**Primary outcomes****1****Description**

Pain severity

**Timepoint**

One, 2 and 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: Patients in first group will receive ropivacaine 0.2% per body weight before extubation.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Patients in second group will receive ropivacaine 0.2% per body weight with tramadol 2 mg/kg before extubation.

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Rasul Akram Hospital

**Full name of responsible person**

Farnad Imani

**Street address**

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

**City**

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Reza Farahmandrad

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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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****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

We have not decided yet

**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**

Not applicable

**Data Dictionary**

Not applicable

**Title and more details about the data/document**

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

**When the data will become available and for how long**

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

**To whom data/document is available**

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

**Under which criteria data/document could be used**

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

**From where data/document is obtainable**

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

**What processes are involved for a request to access data/document**

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

**Comments**