

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of local anesthetic effects of tramadol with lidocaine for circumcision procedure.

Protocol summary

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Summary

In this clinical trial, we compare local anesthetic and analgesic effects tramadol and lidocaine for circumcision. 60 boys, candidate for circumcision procedure with full healthy condition, age between 0-5 years, without any external genital congenital abnormality and without any sensitivity to study drugs included to trial. At group 1, surgeon will inject lidocaine 4 mg/kg, with 25 gauge needle by infiltration at base of penis and at group 2, surgeon will inject tramadol 2 mg/kg, with 25 gauge needle by infiltration at base of penis. We measured patients for pain assessment at the time of intervention, five, ten and twenty minutes after the intervention and the results were presented.

Recruitment status

Recruitment complete

Funding source

Pain Research Center, Shahid Sadoughi University of Medical Science and Health Services

Expected recruitment start date

2011-08-22, 1390/05/31

Expected recruitment end date

2011-10-22, 1390/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106183468N7**

Registration date: **2011-09-22, 1390/06/31**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-09-22, 1390/06/31

Registrant information

Name

Mohammad Reza Hajiesmaeili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

00983516227747-00983517232422

Email address

Scientific title

Comparison of local anesthetic effects of tramadol with lidocaine for circumcision procedure.

Public title

Comparison of tramadol with lidocaine for circumcision procedure.

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: full physical health; age 0-5 years

Exclusion criteria: anatomical malformation; sensitivity to study drug

Age

To **5 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadoughi University of Medical Science and Health Services

Street address

Shahid Bahonar Squire, Yazd, Iran

City

Yazd

Postal code

8919895746

Approval date

2011-08-03, 1390/05/12

Ethics committee reference number

17/1/57201/پ

Health conditions studied

1

Description of health condition studied

circumcision

ICD-10 code

Z41.2

ICD-10 code description

Routine and ritual circumcision

Primary outcomes

1

Description

pain

Timepoint

at intervention-1-5-10-20 minute after intervention

Method of measurement

CHIOPS (Children's Hospital of Eastern Ontario Pain Scale)

2

Description

total analgesic consumption

Timepoint

24 after intervention

Method of measurement

mg/kg consumed ibuprofen

3

Description

time to first analgesic request

Timepoint

time between intervention and first analgesic administratin

Method of measurement

minutes

Secondary outcomes

1

Description

side effects

Timepoint

24 hours after intervention

Method of measurement

observation

Intervention groups

1

Description

at group 1, surgeon will inject lidocain4 mg/kg, with 25 gague needle by infiltration at base of penis.

Category

Other

2

Description

at group 2, surgeon will inject tramadol 2 mg/kg, with 25 gague needle by infiltration at base of penis.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Afshar Hospital

Full name of responsible person

Dr Mohammad Hossein Mirshamsi

Street address

Afshar Hospital, Jomhoori Bol, Yazd, Iran

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pain Research Center

Full name of responsible person

Dr Shekoufeh Behdad

Street address

Shahid Sadoughi Hospital, Yazd, Iran

City

Yazd

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Pain Research Center

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries

Contact**Name of organization / entity**

Shahid Sadoughi University of Medical Sciences and health services, Yazd, Iran

Full name of responsible person

Dr Mohammad Hossein Mirshamsi

Position

Assistant Professor of Surgery

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Full name of responsible person

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Position

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty