Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of Tramadol and Placebo on postoperation pain control in children undergoing Tonsillectomy and Adenotonsillectomy

Protocol summary

Summary

Postoperation pain in children has been remained as a problem. We conducted a double blind Randomized Clinical Trial to study the effect of Tramadol on postoperation pain control in children undergoing Tonsillectomy and Adenotonsillectomy. The study population consisted of 72 children aged 4-10 years that they were candidates for Tonsillectomy and Adenotonsillectomy in Rasul Akram hospital. The children were allocated to 2 groups using block randomization. one group received Tramadol and the other group received a placebo. Anesthetic technique was general and was similar in all cases. After Tonsillectomy: Injection Tramadol(2 mg/kg) was diluted with Saline to 10 cc and was put on both tonsillar fossa for 5 minutes. In control group, Swab soaked in10 cc of normal saline and was given on both tosillar fossa. Patient and anesthesiologist were not aware of the nature of the drug and only operating room technician was aware of the prescribing drug(the study was double blind). The pain was assessed with wong Baker visual scale and were scored from 1 to 6(1.No pain, 6.Sever pain). The patient was assessed at 0(Recovery), 2, 4, 6, 12, 18 and 24 hours after operation and 7 days after that.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013082014199N3**
Registration date: **2013-11-03, 1392/08/12**
Registration timing: **na**

Last update:
Update count: **0**

Registration date

2013-11-03, 1392/08/12

Registrant information

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Recruitment status

Not enough for processing

Funding source

Research Council of Iran University of Medical Sciences

Expected recruitment start date

2012-07-05, 1391/04/15

Expected recruitment end date

2003-07-21, 1382/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Tramadol and Placebo on postoperation pain control in children undergoing Tonsillectomy and Adenotonsillectomy

Public title

The effect of Tramadol on postoperation pain control in children undergoing Tonsillectomy and Adenotonsillectomy

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: Children aged 4-10 years old, who were in ASA physical status classification and have been

placed in groups I and II, and they were candidates for tonsillectomy with or without adenoidectomy. Exclusion criteria: Sensitivity to opioids or local anesthetics, contraindication opioids or local anesthetics, Asthma, kidney disease, liver disease, throat infections, coagulation disorders

Age

From **4 years** old to **10 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **72**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Iran University of Medical Sciences, Department of Ethics

Street address

Iran University of Medical Sciences Central Campus, Shahid Hemmat Highway, Adjacent to Milad Tower, Tehran, Iran

City

Tehran

Postal code

Approval date

2012-07-01, 1391/04/11

Ethics committee reference number

573/ 130/ 91 /د

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Acute pain

Timepoint

At 0(Recovery), 2, 4, 6, 12, 18 and 24 hours after the operation and 7 days after that

Method of measurement

wong Baker visual scale

Secondary outcomes

1

Description

Nausea and Vomiting

Timepoint

At 0(Recovery), 2, 4, 6, 12, 18 and 24 hours after the operation and 7 days after that

Method of measurement

Observation

2

Description

Bleeding

Timepoint

At 0(Recovery), 2, 4, 6, 12, 18 and 24 hours after the operation and 7 days after that

Method of measurement

Observation

Intervention groups

1

Description

Injection Tramadol 2 mg/kg(Manufacturer: Tehran Shimi) was diluted with Saline to 10 cc and was put on both tonsillar fossa for 5 minutes

Category

Prevention

2

Description

Swab soaked in10 cc of normal saline and was given on both tosillar fossa

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasoul Akram Hospital, Ear-Nose-Throat [ENT] operating room, Department of ear-Nose-Throat [ENT]

Full name of responsible person
Dr.Mahmoudreza Alebuye

Street address
Department of ear-Nose-Throat [ENT], Rasool Akram Hospital, Niyaesh Ave., Sattar Khan St., Tehran

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Research Council of Iran University of Medical Sciences

Full name of responsible person
Dr.Seyed Abbas Motevalian

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Iran University of Medical Sciences Central Campus, Shahid Hemmat Highway, Adjacent to Milad Tower, Tehran, Iran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Research Council of Iran University of Medical Sciences

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
Rasoul Akram Hospital, Ear-Nose-Throat [ENT] operating room, Department of ear-Nose-Throat [ENT]

Full name of responsible person
Dr.Mahmoudreza Alebuye

Position
Anesthesiologist

Other areas of specialty/work

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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