Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of topical bupivacaine on pain relieve after tonsillectomy in children referred to Ahvaz Imam Khomeini Hospital in 2013-2014

Protocol summary

Summary

Objectives: To determine the effect of topical bupivacaine on postoperative pain after tonsillectomy 6 hours / determine the effectiveness of topical bupivacaine on postoperative pain after tonsillectomy 24 hours / when the application first dose analgesic effect of the local anesthetic bupivacaine after tonsillectomy. Designed: to check the amount of pain FPRS (Face Pain Rating Scale) is used preoperatively to parents and children will be taught. 6 and 24 hours after surgery are the result of the questionnaire is written sanctity. Term during oral fluids to start the first innings against periods request is recorded. Continues until the completion of the study sample. Method: How to do: After obtaining informed consent from parents of all patients who have undergone tonsillectomy be randomly divided into control and experimental groups. Following surgery for all patients with the same approach, we transferred them to the department for each case is specific. Participants: All patients who have undergone tonsillectomy is supposed to be. Inclusion criteria: 1 - children who have undergone tonsillectomy should be 0.2 - parental consent. Exclusion criteria: 1 - history of any drug allergy. 2 - Lack of parental consent. Interventions: for the treatment group (0.5 mg per kg), local injection of bupivacaine is injected into the tonsillar bed. And for the control group of placebo (sterile water) is injected. The main outcome variables: time to apply the first dose of analgesic / pain 6 hours after surgery / pain 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014041617296N2**
Registration date: **2014-05-05, 1393/02/15**
Registration timing: **retrospective**
Last update:
Update count: **0**

Registration date

2014-05-05, 1393/02/15

Registrant information

Name

Neda Jasemi

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 918 331 2257

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saki_n@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2013-05-06, 1392/02/16

Expected recruitment end date

2013-11-01, 1392/08/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of topical bupivacaine on pain relieve after tonsillectomy in children referred to Ahvaz Imam Khomeini Hospital in 2013-2014

Public title

Effect of topical bupivacaine on pain relieve after tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: children who have undergone tonsillectomy; parental consent to participate in the study. Exclusion criteria: history of any drug allergy; no parental consent.

Age

From **4 years** old to **13 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ahvaz Jundishapur University of Medical Sciences

Street address

Golestan blv- Ahvaz

City

Ahvaz

Postal code

Approval date

2013-05-22, 1392/03/01

Ethics committee reference number

ajums.rec.1392.253

Health conditions studied

1

Description of health condition studied

Tonsilit

ICD-10 code

C09.9

ICD-10 code description

Tonsil, unspecified

Primary outcomes

1

Description

Reduce pain

Timepoint

After surgery

Method of measurement

FPRS(Face Pain Rating Scale)

Secondary outcomes

1

Description

Change pain

Timepoint

After surgery

Method of measurement

FPRS(Face Pain Rating Scale)

Intervention groups

1

Description

Local bupivacaine before surgery intervention group

Category

Treatment - Drugs

2

Description

for the placebo control group (distilled water) was used

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital ,ahvaz jundishapur university medical of sceinces

Full name of responsible person

Street address

ENT unit,Imam Khomeini Hospital ,ahvaz jundishapur university medical of sceinces,ahvaz,iran

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice – Chancellery of Research & Technology Affairs-ahvaz jundishapur university of medical scienc

Full name of responsible person
Dr. Nader Saki
Street address
ENT Department, Imam hospital, ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice – Chancellery of Research & Technology Affairs-ahvaz jundishapur university of medical scienc
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

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Name of organization / entity
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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