

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 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)

Phone

+98 918 331 2257

Email address

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 sourceVice – 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****Contact****Name of organization / entity**

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Neda jasemi

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Fax**Email****Web page address****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*