

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of local injection of Bupivacaine and Normal Saline on post operative pain in children who underwent tonsillectomy

Protocol summary

Summary

Objectives: Comparison of local injection of Bupivacaine and Normal Saline on post operative pain in children who underwent tonsillectomy Design: This double-blind prospective, randomized study will be done among patients with tonsillectomy Setting and conduct: 96 patients scheduled for general anesthesia will be received midazolam 1 mg intravenously 5 min before entering the operating room. Premedication will perform with fentanyl 2 micro-gram/kg. General anesthesia will perform with 4 mg/kg sodium thiopental Inclusion criteria: The parent's parents consent; Age between 5 and 12 years old; ASA class I Exclusion criteria: History of allergy to Bupivacaine; previous complications with general anesthesia; Heart disease; Difficult Intubation Intervention: Groups "one" and "two" will be received 12.5 mg local injection of Bupivacaine or 3 ml of Normal Saline at the beginning of the surgery, respectively. Variables: Postoperative pain and needs for analgesics will measure at 1, 2, 4, 8, 12, 18 and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014080918744N1**

Registration date: **2015-05-10, 1394/02/20**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-05-10, 1394/02/20

Registrant information

Name

Fahime Atigh

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

atigh.f@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2014-11-22, 1393/09/01

Expected recruitment end date

2015-06-05, 1394/03/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of local injection of Bupivacaine and Normal Saline on post operative pain in children who underwent tonsillectomy

Public title

Comparison of local injection of Bupivacaine and Normal Saline on post operative pain in children who underwent tonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The parent's parents consent; Age between 5 and 12 years old; ASA class I Exclusion criteria: History of allergy to Bupivacaine; previous complications with general anesthesia; Heart disease;

Difficult Intubation

Age
From **5 years** old to **12 years** old

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **96**

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
Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address
No. 21, Ave. 1, Golestan Blvd.

City
Ahvaz

Postal code
6135733777

Approval date
2014-07-26, 1393/05/04

Ethics committee reference number
Ajums.REC.1393.146

Health conditions studied

1

Description of health condition studied
Pain

ICD-10 code
R52.0

ICD-10 code description
Acute Pain

Primary outcomes

1

Description
Pain

Timepoint
1,2,4,8,12, 18 and 24 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Opioid Consumption

Timepoint
24 hours after surgery

Method of measurement
Milligram

Intervention groups

1

Description
Bupivacaine: Dose: 12.5 mg Number of using: Once
Factory name: Astra Zeneca Manufacturing Country's Name: France Location prescribed: Local injection
Administration time: At the beginning of the surgery

Category
Treatment - Drugs

2

Description
Normal Saline: Dose: 3 ml Number of using: Once
Factory name: Loghman Manufacturing Country's Name: Iran Location prescribed: Local injection Administration time: At the beginning of the surgery

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Imam Khomeini Educational Hospital

Full name of responsible person
Dr, Fateme Javaherforush

Street address
No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person

Dr. Mostafa Feghhi

Street address

No. 21, Ave. 1, Golestan Blvd.

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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

Vice chancellor for research, Ahvaz Jundishapur
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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

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Position

Resident of Anesthesia

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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