# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

07 Nov 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**

+98 61 1222 0168

**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.

**City**
Ahvaz

**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**
Fahime Atigh

**Position**
Resident of Anesthesia

**Other areas of specialty/work**

**Street address**
No. 12, Enghelab Chamber, Golestan

**City**
Ahvaz

**Postal code**
6135733777

**Phone**
+98 61 1432 5879

**Fax**
+98 61 1432 5879

**Email**
atigh.f@ajums.ac.ir; f.atigh189@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**
Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**
Fahime Atigh

**Position**
Resident of Anesthesia

**Other areas of specialty/work**

**Street address**
No. 12, Enghelab Chamber, Golestan

**City**
Ahvaz

**Postal code**
6135733777

**Phone**
+98 61 1432 5879

**Fax**
+98 61 1432 5879

**Email**
atigh.f@ajums.ac.ir; f.atigh189@yahoo

**Web page address**

## Person responsible for updating data

**Contact**

**Name of organization / entity**
Ahvaz Jundishapur University of Medical Sciences

**Full name of responsible person**
Fahime Atigh

**Position**
Resident of Anesthesia

**Other areas of specialty/work**

**Street address**
No. 12, Enghelab Chamber, Golestan

**City**
Ahvaz

**Postal code**
6135733777

**Phone**
+98 61 1432 5879

**Fax**
+98 61 1432 5879

**Email**
atigh.f@ajums.ac.ir; f.atigh189@yahoo.com

**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*