

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of bupivacaine on pain after tonsillectomy

#### Protocol summary

##### Study aim

the effect of topical administration on pain after tonsillectomy.

##### Design

A clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 96 children aged 5-12 years. For randomization using of random numbers table, hiding method: opaque sealed envelopes

##### Settings and conduct

The study will be done, in Imam Khomeini Hospital in the Ahvaz. Patients who will enter in the study, without awareness of which group they are attending, they will be operated. After anesthesia and 10 minutes before surgery, bupivacaine or placebo will be direct-injected to peritonsillar. When the operate will be ended, patients will be observed at 24 hours. During the hospitalization, the pain will be recorded three times.

##### Participants/Inclusion and exclusion criteria

The inclusion criteria: Tonsillectomy candidate; age between 5-12 years Exclusion criteria : coagulation disorder; acute pharyngitis; active respiratory tract infection

##### Intervention groups

Intervention group1: there are 48of attended patients (according to the inclusion criteria o), who they will receive Bupivacaine 3 milliliter (France Astra Zeneca company) as a direct peritonsillar injection, before Surgery. 10 minutes later surgery will be started. Control group: there are 48of attended patients (according to the inclusion criteria ) who they will not receive any Bupivacaine before surgery (according to the references, if patients did not get the drug, they will not harm and this is acceptable).

##### Main outcome variables

The severity of the pain

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20180909040979N6**

Registration date: **2020-05-14, 1399/02/25**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-05-14, 1399/02/25**

Update count: **0**

#### Registration date

2020-05-14, 1399/02/25

#### Registrant information

##### Name

MARYAM ZAMANKHANI

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 61 3336 4760

##### Email address

zamankhani.m@ajums.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2019-10-24, 1398/08/02

#### Expected recruitment end date

2020-05-24, 1399/03/04

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

The effect of bupivacaine on pain after tonsillectomy

#### Public title

Examination of bupivacaine for pain after tonsillectomy

#### Purpose

Prevention

## **Inclusion/Exclusion criteria**

### **Inclusion criteria:**

tonsillectomy candidate age between 5-12 years

### **Exclusion criteria:**

coagulation disorder ; Symptoms of acute pharyngitis;  
Active upper respiratory tract infection

## **Age**

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

## **Gender**

Both

## **Phase**

3

## **Groups that have been masked**

- Participant
- Care provider
- Outcome assessor
- Data analyser

## **Sample size**

Target sample size: **90**

## **Randomization (investigator's opinion)**

Randomized

## **Randomization description**

Simple randomization Randomization unit: individual  
Randomization tool: with using a random numbers table  
How to create a random sequence: using a random numbers table to read it from top to bottom and the even numbers belong to intervention group and the odd numbers belong to control group. Allocation concealment: using of Sequentially numbered, sealed, opaque envelopes, In this way that the numbers obtained by the random numbers table will be written on the cards respectively. each card will be put inside sealed opaque envelopes. Then envelopes will be numbered and placed in boxes respectively. In the next stage, the patients will enter the group by taking the envelopes respectively (Preparation of the envelopes will be done by the secretary and the physician will not be informed of them)

## **Blinding (investigator's opinion)**

Double blinded

## **Blinding description**

Participants, health care workers in charge of patient care, data collection officials, and those who evaluate the outcome are blind to how they work.

## **Placebo**

Used

## **Assignment**

Parallel

## **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

**Name of ethics committee**

Ethics committee of Ahvaz University of Medical Sciences

#### **Street address**

Ahvaz Jundishapur University of Medical Sciences.,  
Research Deputy., Blvd. Golestan

#### **City**

Ahvaz

#### **Province**

Khouzestan

#### **Postal code**

6193673166

#### **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**

Tonsillectomy

#### **ICD-10 code**

#### **ICD-10 code description**

## **Primary outcomes**

### 1

#### **Description**

pain intensity after tonsillectomy

#### **Timepoint**

6,12,24 hours after surgery

#### **Method of measurement**

Visual Analog Score

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: This group includes 48 patients who entered the study (according to the inclusion criteria ) who injected 3 ml of bupivacaine (the French pharmaceutical company AstraZenka) directly into the space before the operation. They will receive around the tonsils (in the upper and lower bridge of the tonsils) and surgery will begin after 10 minutes.

#### **Category**

Prevention

### 2

#### **Description**

Control group: This group includes 48 patients who entered the study (according to the inclusion criteria ) who will not receive bupivacaine (according to the references, if the drug is not given, the patient will not

be harmed, and this is confirmed).

**Category**

Placebo

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Khomini Hospital

**Full name of responsible person**

Fatemeh Javaherforoosh zadeh

**Street address**

Imam Khomeini Hospital, Azadegan Ave.

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**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Mohammad Badavi, PhD

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Deputy of Research, Ahvaz Jundishapur University of Medical Sciences, 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**

Ahvaz University of Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

Public

**Domestic or foreign origin**

Domestic

**Category of foreign source of funding**

empty

**Country of origin****Type of organization providing the funding**

Academic

**Person responsible for general inquiries****Contact****Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Fatemeh Javaherforoosh zadeh

**Position**

Anesthesiologist

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Anesthesiology

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**Latest degree**

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**Person responsible for updating data****Contact**

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

Anesthesiologist

**Latest degree**

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**Email**

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

Undecided - It is not yet known if there will be a plan to make this available

**Statistical Analysis Plan**

Undecided - It is not yet known if there will be a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available