

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of topical use of bupivacaine and dexamethasone in tonsillar cavity in order to reduce pain after tonsillectomy

#### Protocol summary

##### Study aim

Determining the Effect of Topical Use of Bupivacaine and Dexamethasone in Tonsillar Cavity to Reduce Post-Tonsillectomy Pain

##### Design

This study is a randomized clinical trial is a double-blind, for patients undergoing tonsillectomy, in Amir Kabir Hospital . In this study, 60 patients undergoing tonsillectomy using block randomization (Permuted block randomization ) divided 2 Groups equal use of gases soaked in combination with dexamethasone and bupivacaine or using gses soaked in saline in the tonsillar cavity,

##### Settings and conduct

In intervention group a 1 mg / kg of solution of bupivacaine 0.5 percent plus 1 mg of dexamethasone per kilogram (maximum 8 mg dexamethasone) and use normal saline to bring it to 10 cc and transfer to 2 gases and immediately after the tonsillectomy put it in the tonsillar cavity for ten minutes . Blindness due to its double blindness is that in this study only an otolaryngologist responsible for the study is aware of the type of study and the studied groups.

##### Participants/Inclusion and exclusion criteria

log in : Patients with frequent pharyngitis Patients with complaints of bad breath and chronic sore throat Patients with chronic tonsillitis Non arrival: Suspect malignancy Asymmetric of tonsiles Coagulation disorders in patients

##### Intervention groups

Intervention group: 30 patients immediately after tonsillectomy place a gas soaked with bupivacaine and dexamethasone into the tonsillar cavity of each side for 10 minutes. Control group: 30 patients immediately after tonsillectomy, place a gas soaked with 10 cc normal saline in the tonsillar cavity of each side.

##### Main outcome variables

Patients' pain score is measured by checklist in three replicates at 12 hours, 24 hours and one week after the

intervention.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20181226042142N1**

Registration date: **2019-03-16, 1397/12/25**

Registration timing: **prospective**

Last update: **2019-03-16, 1397/12/25**

Update count: **0**

##### Registration date

2019-03-16, 1397/12/25

##### Registrant information

##### Name

Mohammadreza Mohammadi

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 4633 5314

##### Email address

www.mm80091@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-05-23, 1398/03/02

##### Expected recruitment end date

2019-10-30, 1398/08/08

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of topical use of bupivacaine and dexamethasone in tonsillar cavity in order to reduce pain after tonsillectomy

### Public title

The effect of topical use of bupivacaine and dexamethasone in tonsillar cavity in order to reduce pain after tonsillectomy

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Patients with frequent pharyngitis Patients with complaints of chronic bad breath and sore throat

Patients with chronic tonsillitis

#### Exclusion criteria:

Coagulation disorders in patients Suspect malignancy Asymmetric of tonsils

### Age

From 2 years old

### Gender

Both

### Phase

3

### Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

### Sample size

Target sample size: 60

### Randomization (investigator's opinion)

Randomized

### Randomization description

This study is a randomized, double-blind clinical trial for patients undergoing tonsillectomy in Amirkabir Hospital. A total of 60 patients candidates for Tonsillectomy were randomly divided into two equal groups that using gases soaked dexamethasone and bupivacaine , or normal-saline in order to insert in the tonsillar cavity .

### Blinding (investigator's opinion)

Double blinded

### Blinding description

In this study, only an otolaryngologist who is responsible for the study is aware of the type of study and the studied groups, while the patients , are not aware.also intern responsible for the plan that is responsible for filling the questionnaire ; it is not aware of the type of groups in terms of impacted drugs, and only knows the groups based on A and B, and fills the questionnaire on the basis of it.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Arak University of Medical Sciences

##### Street address

Sardasht - Basij Square- Arak University of Medical Sciences

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

#### Approval date

2019-02-24, 1397/12/05

#### Ethics committee reference number

IR.ARAKMU.REC.1397.270

## Health conditions studied

### 1

#### Description of health condition studied

The Effect of Topical Use of Bupivacaine and Dexamethasone in Tonsillar Cavity in order to Reduce Pain After Tonsillectomy

#### ICD-10 code

J35

#### ICD-10 code description

Chronic diseases of tonsils and adenoids

## Primary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

12 hours later and 24 hours later and one week after the intervention

#### Method of measurement

Based on checklist

### 2

#### Description

Number of nausea and vomiting

#### Timepoint

12 hours later and 24 hours later and one week after the intervention

#### Method of measurement

Based on checklist

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: After obtaining informed consent, 30 patients immediately after tonsillectomy place a gas soaked with bupivacaine and dexamethasone into the tonsillar cavity of each side for 10 minutes. In patients, they are given a 1 mg / kg of solution of bupivacaine 0.5 percent plus 1 mg of dexamethasone per kilogram (maximum 8 mg dexamethasone) and use normal saline to bring it to 10 cc and transfer to 2 gases and immediately after the tonsillectomy put it in the tonsillar cavity for ten minutes. Then, the pain score of patients in each of the two groups was measured in three replicates at 12 hours, 24 hours and one week after the intervention based on the checklist prepared.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: After obtaining informed consent, 30 patients immediately after tonsillectomy, place a gas soaked with 10 cc normal saline in the tonsillar cavity of each side. Then, the pain levels of the patients in the two groups, measured in three replicates, 12 hours later, 24 hours later and one week after the intervention based on the checklist.

#### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Amir Kabir Hospital in Arak

##### Full name of responsible person

Mohammad Reza Mohammadi

##### Street address

Shahid Shiroodi Street - Nursing Square

##### City

Arak

##### Province

Markazi

##### Postal code

3848176941

##### Phone

+98 86 3313 4715

##### Email

Rsearch@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Mohammad Arjmandzadegan

##### Street address

sardasht - The Effect of Topical Use of Bupivacaine and Dexamethasone in Tonsillar Cavity in order to Reduce Pain After Tonsillectomy

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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

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Mohammadreza Mohammadi

##### Position

Medical student

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

No. 29, Shahid Hamid Reza Shamsi Avenue, Imam Khomeini Street

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##### Province

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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