

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

City

Arak

Province

Markazi

Postal code

3848176941

Phone

+98 86 3417 3645

Email

Rsearch@arakmu.ac.ir

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

City

Khomein

Province

Markazi

Postal code
3881963356
Phone
+98 86 4633 5314
Fax
Email
www.mm80091@gmail.com

Person responsible for scientific 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
City
Khomein
Province
Markazi
Postal code
3881963356
Phone
+98 86 4633 5314
Fax
Email
www.mm80091@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person

Mohammad Reza Mohammadi
Position
Medical student
Latest degree
A Level or less
Other areas of specialty/work
Ear, Nose, and Throat
Street address
shahid hamidreza shamsi alley - Emam khomeini street
City
khomein
Province
Markazi
Postal code
3881963356
Phone
+98 86 4633 5314
Email
www.mm80091@gmail.com

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