

Clinical Trial Protocol

Iranian Registry of Clinical Trials

25 Jul 2026

Comparison of diphenhydramine and placebo on the side effect of tonsillectomy

Protocol summary

Study aim

Comparison of diphenhydramine and placebo on the side effect of tonsillectomy

Design

Clinical trial with control group, with parallel groups, single-blind, randomized, phase 3 on 66 patients. The random number table was used for randomization.

Settings and conduct

This study is being performed at Valiasr Hospital in Birjand, South Khorasan Province. Sixty-six patients were randomly assigned to two groups: adenotonsillectomy surgery receiving diphenhydramine and normal saline. Then, the amount of pain in patients in two groups at 0, 24, 12, 6 hours after surgery, postoperative complications in patients including: the amount of bleeding during and after surgery; The duration of hospitalization in the ward will be nausea and vomiting, which will be examined by the nurse after the operation and one day after the operation without the patient's knowledge of the type of medication received.

Participants/Inclusion and exclusion criteria

patients who were candidates for adenotonsillectomy surgery at Valiasr Hospital in Birjand in 1399. Inclusion criteria: ages 5 to 50 years, patients with ASA class 1 and 2, no history of liver or kidney disease, no disease: bronchial asthma, bladder disease, no pregnancy and lactation, no gestational hypertension or preeclampsia. Exclusion criteria; patient withdrawal, coagulation disorders, concomitant surgery with other oral and pharyngeal problems, known allergic reactions to antihistamines, benzodiazepines, or local anesthetics, and acute laryngeal infection.

Intervention groups

Patients were randomly assigned to adenotomectomy with two groups receiving diphenhydramine as a anesthetic in the tonsil bed at a dose of 1.25 mg / kg up to a maximum of 8 mg 5 minutes before surgery and patients in the normal saline control group with the same volume in bed. The tonsils will be injected.

Main outcome variables

Pain, nausea, vomiting, sore throat.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190618043934N5**

Registration date: **2020-07-04, 1399/04/14**

Registration timing: **registered_while_recruiting**

Last update: **2020-07-04, 1399/04/14**

Update count: **0**

Registration date

2020-07-04, 1399/04/14

Registrant information

Name

Zabihullah Mohaghegh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 56 3232 3232

Email address

oabstudent@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-19, 1399/03/30

Expected recruitment end date

2020-07-20, 1399/04/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of diphenhydramine and placebo on the side effect of tonsillectomy

Public title

The effect of diphenhydramine on adenotonsillectomy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Age between 5 and 50 years Patients with ASA classes 1 and 2 No history of liver disease Lack of bronchial asthma Lack of bladder disease No pregnancy and lactation Lack of blood pressure during pregnancy or preeclampsia No history of kidney disease

Exclusion criteria:

Coagulation disorder Simultaneous surgery of the patient with other oral and pharyngeal problems Allergic reactions known to antihistamines Allergic reactions known to benzodiazepines or topical anesthetics Having an acute pharyngeal infection

Age

From **5 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

Participants in the study will be randomly divided into intervention and control groups using a random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Assessor of the outcome (nurse) without knowing the placement of the individual in the study group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics Committee of Birjand University of Medical Sciences

Street address

Moallem BLV

City

Birjand

Province

South Khorasan

Postal code

9717811674

Approval date

2020-06-10, 1399/03/21

Ethics committee reference number

IR.BUMS.REC.1399.071

Health conditions studied**1****Description of health condition studied**

Tonsillitis

ICD-10 code

J03

ICD-10 code description

Acute tonsillitis

Primary outcomes**1****Description**

Pain

Timepoint

0, 6, 12 and 24 hours after surgery

Method of measurement

Using the VAS Scale

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients taking diphenhydramine as a anesthetic in the tonsil bed receive 1.25 mg / kg up to a maximum of 8 mg 5 minutes before surgery.

Category

Treatment - Drugs

2**Description**

Control group: Normal saline patients receive the same amount of diphenhydramine in the tonsil bed 5 minutes before surgery.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Valie-asr Hospital_Birjand

Full name of responsible person

Nastaran Jalili

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Birjand University of Medical Sciences

Full name of responsible person

Dr. Tooba Kazemi

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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

Birjand 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

Birjand University of Medical Sciences

Full name of responsible person

Zabihullah Mohaghegh

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr MohammadReza Mofatteh

Position

Member of the Faculty

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Other areas of specialty/work

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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