Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 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. Excusion 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 adenotonecylectomy 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
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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
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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
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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