

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of pre-treatment with diphenhydramine on the complications of recovery in minor ear, nose and throat surgeries (tympanoplasty).

Protocol summary

Study aim

Reducing the effects of recovery (nausea, vomiting and pain) after tympanoplasty surgery with the help of diphenhydramine

Design

A total of 100 patients will be selected as a research sample, then divided into two groups of intervention and control. The intervention group will receive Diphenhydramine and the control group will receive normal saline as a placebo. The study is a randomized, double-blind, placebo-controlled clinical trial.

Settings and conduct

The study will be performed in the recovery department of Imam Reza Hospital in Tabriz. The variables of nausea, vomiting and pain will be completely examined and recorded by the anesthesiologist in both groups. The severity of postoperative nausea and vomiting in recovery at 3, 6, 12, 18 and 24 hours and based on scoring (0 = no nausea and vomiting, 1 = nausea, 2 = vomiting and 3 = vomiting more than 2 times) will be reviewed and the severity of the pain at the same time will be assessed by a four-digit verbal rating scale. In this study, patients and anesthesiologists are blinded to the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Conscious patients over the age of 18 with ASA grade, class I&II
Lack of sensitivity to the study drug
Exclusion criteria: Having middle ear disease
History of nausea and vomiting over the past 24 hours
Pregnant and breastfeeding woman.

Intervention groups

Intervention group: In this group, 25 mg of diphenhydramine will be injected before the start of anesthesia. Control group: In this group only 5 cc normal saline (as a placebo) will be injected completely with the specifications of the drugs of the intervention group before the start of anesthesia.

Main outcome variables

Severity of pain, Severity of nausea and vomiting.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150217021121N4**

Registration date: **2020-04-28, 1399/02/09**

Registration timing: **registered_while_recruiting**

Last update: **2020-04-28, 1399/02/09**

Update count: **0**

Registration date

2020-04-28, 1399/02/09

Registrant information

Name

Reza Movassaghi Gargari

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-20, 1399/02/01

Expected recruitment end date

2020-09-22, 1399/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pre-treatment with diphenhydramine on the complications of recovery in minor ear, nose and throat surgeries (tympanoplasty).

Public title

The effect of diphenhydramine on recovery complications in tempolanoplasty surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Conscious patients over the age of 18 with ASA grade, class I&II Lack of sensitivity to the study drug

Exclusion criteria:

Having middle ear disease Patients with a history of pelvic surgery History of nausea and vomiting over the past 24 hours Pregnant and breastfeeding woman

Age

From **18 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients wishing to participate in the study who meet the inclusion criteria will be selected through convenient sampling and then randomly assigned to two control and intervention groups using Randlist software

Blinding (investigator's opinion)

Double blinded

Blinding description

The anesthesiologist who is responsible for the patients management to induce anesthesia will administer the medicine(s) via coded syringes which have been prepared previously and therefore he/she will not be aware of the injected drug. Meanwhile the anesthesia nurse who is responsible for collection of patients' information and study variables and is unaware of the administered drug will fill the check- list during surgery and in the recovery room. Also the patient is unaware of the injected medicine.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Tabriz University of Medical Sciences

Street address

Faculty of Medicine, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614766

Approval date

2020-03-09, 1398/12/19

Ethics committee reference number

IR.TBZMED.REC.1398.1292

Health conditions studied

1

Description of health condition studied

Postoperative nausea and vomiting

ICD-10 code

Y84

ICD-10 code description

Other medical procedures as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

2

Description of health condition studied

Postoperative pain

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Severity of postoperative nausea and vomiting

Timepoint

Recovery and at 3, 6, 12, 18 and 24 hours postoperatively

Method of measurement

scoring by (0=non, 1=nausea, 2=vomiting, 3=vomiting >2 times)

2

Description

Severity of postoperative pain

Timepoint

Recovery and at 3, 6, 12, 18 and 24 hours postoperatively

Method of measurement

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In this group, 25 mg of diphenhydramine will be injected before the start of anesthesia.

Category

Treatment - Drugs

2

Description

Control group: In this group only 5 cc normal saline (as a placebo) will be injected completely with the specifications of the drugs of the intervention group before the start of anesthesia.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza hospital

Full name of responsible person

Reza Movvassaghi

Street address

Department of Anesthesiology, Faculty of Medical Sciences, Golgasht Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr Abolghasem Joyban

Street address

Vice chancellor for research, Daneshgah street, Tabriz

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Tabriz

Province

East Azarbaijan

Postal code

5165665931

Phone

+98 41 3335 7310

Fax

+98 41 3335 7310

Email

research-vice@tbzmed.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Reza Movvassaghi

Position

Consultant

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Departement of Anesthesiology, Faculty of Medicine, Golgasht Street

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Reza Movvassaghi

Position

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All collected deidentified IPD, IPD collected for the primary outcome measure are to be shared

When the data will become available and for how long

Starting 6 months after publication

To whom data/document is available

Documents will be available for people working in academic institutions and also people working in businesses.

Under which criteria data/document could be used

There will be no specific limitations to the utilization of the data .

From where data/document is obtainable

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rz_movassaghi@yahoo.com

What processes are involved for a request to access data/document

Applicants will access the data from the present study by sending an email to the responsible author for a maximum of one week.

Comments

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Reza Movvassaghi

Position

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Latest degree

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Other areas of specialty/work

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