Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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 tempanoplasty 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 salin 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
Faculity 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

Four Numerical Verbal Rating Scale

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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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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Person responsible for updating data

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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
Dr .Reza Movassaghi, Department of Anesthesiology, Faculty of Medicine, Golgasht Street, Tabriz East Azarbaijan Islamic Republic of Iran Phone+98 413 3341994 Fax+98 41 33341994 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