

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The effect of different doses of Granisetron on preventing postoperative shivering in patients undergoing septoplasty under general anesthesia

Protocol summary

Summary

The aim of this study is to determine the effect of different doses of Granisetron on preventing postoperative shivering in septoplasty patients. In a randomized clinical trial 90 patients with age 18-60 yr and ASA class 1-2 who have elective septoplasty randomly allocate in three groups. Group A receive 1 mg granisetron, group B 3 mg and group C 5 ml normal saline. Before induction of general anesthesia, the prepared solution will be administered intravenously. Same standard general anesthesia will be used in all patients. All patients will be monitored according to ASA standards. In PACU all patients will be covered with blanket and receive oxygen by face mask and will be monitored. Anesthesiologist who is not aware about patients group, will record the shivering, nausea, vomiting and pain. In addition any other complications such as hemodynamic alteration will be record. In patients with shivering, In addition to o2 therapy, they will warm and in patients with shivering grade 3 or more petidine (25mg IV) every 20 minute in maximum 3 doses will be used.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201411173915N11**

Registration date: **2014-12-04, 1393/09/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-12-04, 1393/09/13

Registrant information

Name

Manizheh Mostafa Gharehbaghi

Name of organization / entity

Tabriz University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Research vice chancellor for Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-21, 1393/01/01

Expected recruitment end date

2015-03-20, 1393/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of different doses of Granisetron on preventing postoperative shivering in patients undergoing septoplasty under general anesthesia

Public title

The effect of different doses of Granisetron on preventing post-operative shivering in septoplasty

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age 18-60 yr; ASA class 1-2; elective septoplasty surgery. Exclusion criteria: cardio-respiratory diseases; infections; body temperature less than 36.5°C and more than 38°C; allergy to serotonin antagonist

drugs.

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Tabriz University of Medical Sciences

Street address

Golgasht street

City

Tabriz

Postal code

Approval date

2014-03-10, 1392/12/19

Ethics committee reference number

9366

Health conditions studied

1

Description of health condition studied

Shivering after septoplasty

ICD-10 code

Y40-Y84

ICD-10 code description

Complications of medical and surgical care

Primary outcomes

1

Description

Post operative shivering

Timepoint

Till 2 hours after surgery

Method of measurement

Clinical assessment

Secondary outcomes

1

Description

Need for petidine administration

Timepoint

Till 2 hours after surgery

Method of measurement

Clinical assessment

Intervention groups

1

Description

Group A: intravenous granisetron 1 mg diluted with 5 ml saline normal before induction of general anesthesia

Category

Treatment - Drugs

2

Description

Group B: intravenous granisetron 3 mg diluted with 5 ml normal saline before induction of general anesthesia

Category

Treatment - Drugs

3

Description

Group C: 5 ml intravenous saline normal before induction of general anesthesia

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Dr Ali Peirovifar

Street address

Golgasht Street

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice Chancellor for Tabriz University of
Medical Sciences

Full name of responsible person

Dr Farhoodi

Street address

Golgasht street

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Research Vice Chancellor for Tabriz University of Medical
Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty