

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Plasil, Ondansetron, and Dexamethasone on nausea and vomiting in Children candidate for tonsillectomy

Protocol summary

Summary

The aim of the study: Comparison of the effect of Plasil, Ondansetron, and Dexamethasone on nausea and vomiting in Children candidate for tonsillectomy. Study design: After explaining the purpose of the study and obtaining the informed consent, patients will be allocated into A, B and C groups. Randomization will be performed using random block sizes of 3. The study is single-center, single blind and phase 3 trial and patients and physician will be blind about the type of injection drug. Inclusion criteria: Children from 6 to 12 years old candidate for tonsillectomy. Exclusion criteria: Coagulopathy; congenital heart disease; drug allergies; anatomical anomalies; obstruction of respiratory airway. Sample size: 120 patients will participate in the study with 40 patients in each group. Interventions: Plasil 0.1-0.2 mg/kg IM, ondansetron 0.15 mg/kg/dose IV, Dexamethasone 0.5 mg/kg IV. Primary outcomes: nausea and vomiting

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017060834386N1**

Registration date: **2017-09-16, 1396/06/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-16, 1396/06/25

Registrant information

Name

Negar Hamidi

Name of organization / entity

Islamic Azad University of Shahrood

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research and technology, Islamic Azad University of Shahrood

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Plasil, Ondansetron, and Dexamethasone on nausea and vomiting in Children candidate for tonsillectomy

Public title

The effect of Plasil, Ondansetron, and Dexamethasone on nausea and vomiting

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Children from 6 to 12 years old candidate for tonsillectomy Exclusion criteria: Coagulopathy; congenital heart disease; drug allergies; anatomical anomalies; obstruction of respiratory airway.

Age

From **6 years** old to **10 years** old

Gender

Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **120**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Islamic Azad University of Shahrood

Street address

Islamic Azad University of Shahrood, Tehran Blvd, Shahrood

City

Shahrood

Postal code

3613773955

Approval date

2017-05-16, 1396/02/26

Ethics committee reference number

IR.IAU.SHAHROOD.REC.1396.1

Health conditions studied

1

Description of health condition studied

Tonsillectomy

ICD-10 code

J35.3

ICD-10 code description

Hypertrophy of tonsils with hypertrophy of adenoids

Primary outcomes

1

Description

Nausea

Timepoint

every hours, until 6 hours after surgery

Method of measurement

Observation

2

Description

Vomiting

Timepoint

every hours, until 6 hours after surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention 1: Plasil 0.1-0.2 mg/kg IM

Category

Treatment - Drugs

2

Description

Intervention 2: Ondansetron 0.15 mg/kg/dose IV

Category

Treatment - Drugs

3

Description

Intervention 3: Dexamethasone 0.5 mg/kg IV

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

khatam Alanbia Hospital of Shahrood

Full name of responsible person

Yousef Kolukhi

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khatam Alanbia Hospital, Tehran Blvd, Shahrood

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology, Islamic Azad University of Shahrood

Full name of responsible person
Saheballi Manafi

Street address
Islamic Azad University of Shahroud, Tehran Blvd

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Shahroud

Grant name

Grant code / Reference number

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

Title of funding source
Vice chancellor for Research and Technology, Islamic Azad University of Shahroud

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

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Other areas of specialty/work

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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