

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 2026

### “Effect of supplemental oxygen on post-tonsillectomy nausea and vomiting

#### Protocol summary

##### Summary

Objective:nausea and vomiting are one of the most common complications after tonsillectomy,with or without adenoidectomy in pediatric population.administration of supplemental oxygen 80% during surgery, has been shown to affect on reducing the incidence of postoperative nausea and vomiting. The purpose of this study was to test the efficacy of supplemental oxygen 80% during tonsillectomy on postoperative nausea and vomiting. Material and methods:One hundred two children scheduled for tonsillectomy,with or without adenoidectomy(Exclusion criteria were: diabetes mellitus or kidney disease,immune deficiency, gastroesophageal reflux disease, metabolic disorders,anemia, antiemetic therapy and craniofacial abnormality) under general anesthesia, randomly assigned to two groups: group1:administration of oxygen 30% and group2:administration of oxygen 80%.incidence of postoperative nausea and vomiting assessed and compared in 0-2, 2-6 and 6-24 hours after surgery in two groups. Results:incidence of post tonsillectomy nausea and vomiting in group 1 was: 13/72% in first 2 hours , 1/96% in 2-6hours and 1/96% in 6-24 hours after surgery and in group 2 was: 3/92%% in first 2 hours , 0 in 2-6hours and 1/96% in 6-24 hours after surgery. Conclusion:We found administration of supplemental oxygen 80% did not have statistically difference in post tonsillectomy nausea and vomiting between two groups( $p=0/08$  but it had beneficial effect in reducing postoperative nausea and vomiting in first 2 hours after surgery in group2.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201012122893N3**

Registration date: **2014-06-02, 1393/03/12**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2014-06-02, 1393/03/12

##### Registrant information

###### Name

Poopak Izadi

###### Name of organization / entity

Shahed University

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8896 9437

###### Email address

izadi@shahed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Shahed University

##### Expected recruitment start date

2013-05-01, 1392/02/11

##### Expected recruitment end date

2013-10-01, 1392/07/09

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

“Effect of supplemental oxygen on post-tonsillectomy nausea and vomiting

##### Public title

“Effect of supplemental oxygen on post-tonsillectomy nausea and vomiting

##### Purpose

Prevention

## Inclusion/Exclusion criteria

Inclusion criteria:all children 5-15 years old scheduled for tonsillectomy; Exclusion criteria were: comorbidities had an influence on postoperative nausea and vomiting such as diabetes mellitus or kidney disease,immune deficiency, gastroesophageal reflux disease, metabolic disorders,anemia, antiemetic therapy and craniofacial abnormality.

## Age

From **5 years** old to **15 years** old

## Gender

Both

## Phase

N/A

## Groups that have been masked

*No information*

## Sample size

Target sample size: **102**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Not blinded

## Blinding description

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

ethics in medical research committee

##### Street address

Shahed University

##### City

Tehran

##### Postal code

#### Approval date

2013-10-05, 1392/07/13

#### Ethics committee reference number

41/181320

## Health conditions studied

### 1

#### Description of health condition studied

tonsillectomy candidates

#### ICD-10 code

J35.3

#### ICD-10 code description

Hypertrophy of tonsils with hypertrophy of adenoids

## Primary outcomes

### 1

#### Description

nausea and vomiting

#### Timepoint

first 24 hours after surgery

#### Method of measurement

observation and assessment with statistical methods

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

group1:routine oxygen administration oxygen 30% with balanced nitrogen oxide70% all the time of anesthesia from induction till recovery. Group2:supplemental oxygen administration 80% all the time of anesthesia.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Shahid Mostafa Khomeini Hospital

##### Full name of responsible person

Poopak Izadi

##### Street address

##### City

Tehran

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Shahed University

##### Full name of responsible person

Poopak Izadi

##### Street address

Shahid Mostafa Khomeini Hospital,Italia Ave.,Keshavarz Blvd.,Tehran

##### City

Tehran

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Shahed University

#### 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**

Shahed University

**Full name of responsible person**

Poopak Izadi

**Position**

Otolaryngologist

**Other areas of specialty/work**

**Street address**

Shahid Mostafa Khomeini Hospital, Italia

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izadi@shahed.ac.ir

**Web page address**

## Person responsible for scientific inquiries

### Contact

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**Full name of responsible person**

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**Position**

otolaryngologist

**Other areas of specialty/work**

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## Person responsible for updating data

### Contact

**Name of organization / entity**

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**Full name of responsible person**

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**Position**

assistant professor

**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*