Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Investigating the effect of half percent oxymetazoline nasal drops on cough, sore throat and bleeding in children after tonsillectomy

Protocol summary

Study aim
Determining the effect of oxymetazoline on cough, sore throat and bleeding in children undergoing tonsillectomy

Design
The randomized, double-blind clinical trial, with the parallel groups, Phase 3 on 88 patients

Settings and conduct
In this randomized double-blind clinical trial study, 88 eligible children, referred to Al-Zahra Hospital in Isfahan, will be included in the study and will be randomly divided into two groups. Oxymetazoline 0.5% nasal spray will be prescribed for patients in the first group, and distilled water spray will be prescribed for the second group. The intervention will be performed in such a way that the patient and the researcher will not have any knowledge of the type of intervention and double-blind conditions will be established. Then the cough, sore throat and bleeding rate of the children will be evaluated and compared between the two groups.

Participants/Inclusion and exclusion criteria
The inclusion criteria involved patients aged 6-12 years, candidates of tonsillectomy, having ASA I or II. Exclusion criteria include having hypertension, sensitivity to oxymetazoline, and taking painkillers, antinausea, steroids, and antihistamines within 15 hours before surgery.

Intervention groups
Intervention group: In this group, 0.5% Oxymetazoline nasal spray is prescribed as one puff in each nostril immediately after the induction of anesthesia. Then, 12 hours after the start of tonsillectomy, nasal spray is prescribed again in both nostrils. Control group: In this group, distilled water spray is prescribed immediately after induction of anesthesia as one puff in each nostril. Then, 12 hours after the start of tonsillectomy, nasal spray is prescribed again in both nostrils.

Main outcome variables
Cough; Sore throat; Bleeding rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20110528006617N7**
Registration date: **2022-08-16, 1401/05/25**
Registration timing: **prospective**

Last update: **2022-08-16, 1401/05/25**
Update count: **0**

Registration date
2022-08-16, 1401/05/25

Registrant information

Name
Mehrdad Masoudifar

Name of organization / entity
Esfahan University of medical sciences

Country
Iran (Islamic Republic of)

Phone
+98 31 1268 2007

Email address
masoudifar@med.mui.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-09-22, 1401/06/31

Expected recruitment end date
2023-02-20, 1401/12/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of half percent oxymetazoline nasal drops on cough, sore throat and bleeding in children after tonsillectomy

Public title
The effect of oxymetazoline nasal drops on cough, sore throat and bleeding in children after surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Candidate for tonsillectomy surgery Ages between 6-12 years American Society of Anesthesiology (ASA) classification equal to I or II Parents' consent to participate in the study

Exclusion criteria:
Having hypertension Sensitivity to oxymetazoline Children who received analgesics, anti-nausea, asteroids, and antihistamines during the 15 hours prior to surgery Taking painkillers, antinausea, steroids, and antihistamines within 15 hours before surgery

Age
From **6 years** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Data analyser

Sample size
Target sample size: **88**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 88 eligible children are randomly selected. For this, the letter A is written on 40 sheets, and the letter B is written on 40 sheets and each of them is placed in an envelope. Each The child's parents is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of two groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
To comply with the blinding terms, both nasal sprays are prepare in advance by the pharmacist in the same shape, color, and smell and in the same boxes with the same volume and are coded with A, B labels and are made available daily to the surgical team in the operating room.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2021-08-15, 1400/05/24

Ethics committee reference number
IR.MUI.MED.REC.1400.377

Health conditions studied

1

Description of health condition studied
Tonsillectomy surgery

ICD-10 code
J35.01

ICD-10 code description
Chronic tonsillitis

Primary outcomes

1

Description
Bleeding rate

Timepoint
During surgery and hospitalization in the ward

Method of measurement
Measuring the suction bottle and weightening of bloody gazes

2

Description
Sore throat

Timepoint
upon entering the recovery room and at minutes 15, 30, 45, and 60 of recovery as well as upon entering the ward and minutes 15, 30, 45, and 60 being in the ward

Method of measurement
Visual Analogue Scale (VAS)

3

Description
Cough

Timepoint
From admission to recovery room until 24 hours after

extubation

Method of measurement

Observational

Secondary outcomes

1

Description

Heart rate

Timepoint

The beginning of recovery and at minutes 15, 30, 45, and 60 of recovery

Method of measurement

Monitoring device

2

Description

Systolic blood pressure

Timepoint

The beginning of recovery and at minutes 15, 30, 45, and 60 of recovery

Method of measurement

Monitoring device

3

Description

Diastolic blood pressure

Timepoint

The beginning of recovery and at minutes 15, 30, 45, and 60 of recovery

Method of measurement

Monitoring device

Intervention groups

1

Description

Intervention group: In this group, 0.5% Oxymetazoline nasal spray (Raha Pharmaceutical Company) is prescribed as one puff in each nostril immediately after the induction of anesthesia. Then, 12 hours after the start of tonsillectomy, nasal spray is prescribed again in both nostrils.

Category

Treatment - Drugs

2

Description

Control group: In this group, distilled water spray is prescribed immediately after induction of anesthesia as one puff in each nostril. Then, 12 hours after the start of tonsillectomy, nasal spray is prescribed again in both nostrils.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital, Isfahan

Full name of responsible person

Mehrdad Masoudifar

Street address

Department of Anesthesiology, Al-Zahra Hospital, Hezar Jarib Street.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3620 2020

Email

masoudifar@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mansour Siavash Dastjerdi

Street address

Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 8597

Email

dean@med.mui.ac.ir

Grant name

Grant code / Reference number

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

No

Title of funding source

Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Mehrdad masoudifar

Position
Associate Professor of Anesthesiology

Latest degree
Subspecialist

Other areas of specialty/work
Anesthesiology

Street address
Department of Anesthesiology, Al-Zahra Hospital, Hezar Jarib Street.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3620 2020

Email
masoudifar@med.mui.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mehrdad masoudifar

Position
Associate Professor of Anesthesiology

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Subspecialist

Other areas of specialty/work
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Province
Isfehan

Postal code
8174673461

Phone
+98 31 3620 2020

Email
masoudifar@med.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Sheida Mosharaf

Position
Non-faculty specialist doctor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Department of Anesthesiology, Al-Zahra Hospital, Hezar Jarib Street.

City
Isfahan

Province
Isfehan

Postal code
8174673461

Phone
+98 31 3620 2020

Fax

Email
Sheida.mosharaf@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available