Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Investigating the effect of preventive dose of dexamethasone on pain, nausea, frequent vomiting and postoperative restlessness in patients undergoing septorhinoplasty.

Protocol summary

Study aim

Determining and comparing the average intensity of pain, nausea, vomiting and restlessness after surgery in patients undergoing septoplasty, rhinoplasty and septorhinoplasty using prompt dose of dexamethasone after induction of anesthesia.

Design

In this triple blind phase3, randomized controlled clinical trial with parallel groups, 70 patients who are candidates for septorhinoplasty are distributed in two groups of 35 by simple random allocation method. In the first group, 0.1 mg/kg of intravenous dexamethasone is injected, and in the control group, the same volume of normal saline is injected.

Settings and conduct

This triple blind clinical trial study is conducted in Al-Zahra Hospital of Isfahan in 2024. The patients, researcher and data collector are unaware of the type of intervention. Patients randomly allocated to two groups of intervention and control.

Participants/Inclusion and exclusion criteria

Inclusion critera include: candidates for septorhinoplasty, age range 88 to 55 years, agree to participate in the study, ASA class one and two, and elective surgery. The exclusion criteria include: suffering from an underlying disease, history of long-term use of anti-nausea and vomiting drugs and corticosteroids, and history of smoking, suffering from reflux, occurrence of a disorder during the operation that requires medical intervention, changing the operation technique or anesthesia to There are various reasons and the impossibility of collecting data until the end of the study due to reasons such as the death of the patient during the operation.

Intervention groups

After induction of anesthesia in the first group, dexamethasone 0.1 mg per kg (about 8 mg) is injected slowly intravenously for each adult. In the control group, normal saline is injected with the same volume and method.

Main outcome variables

Post operative Pain, Nausea and vomiting, Restlessness after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240208060937N1**
Registration date: **2024-02-18, 1402/11/29**
Registration timing: **prospective**

Last update: **2024-02-18, 1402/11/29**
Update count: **0**

Registration date

2024-02-18, 1402/11/29

Registrant information

Name

Amii Taravati

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3669 2174

Email address

amir.taravati44@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-20, 1402/12/01

Expected recruitment end date

2024-09-20, 1403/06/30

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Investigating the effect of preventive dose of dexamethasone on pain, nausea, frequent vomiting and postoperative restlessness in patients undergoing septorhinoplasty.

Public title
Comparison effect of Dexamethasone on pain, nausea and vomiting and restlessness after rhinoplasty.
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
ASA class I and II Absence of underlying diseases including respiratory diseases, cardiovascular diseases and diabetes No long-term use of anti-nausea and vomiting drugs and corticosteroids Not smoking Electiveness of surgery Not having reflux Patient consent to participate in the study
Exclusion criteria:
Occurrence of disorder during operation that requires medical intervention Changing the operation technique or anesthesia for various reasons The impossibility of collecting data until the end of the study, including the death of the patient during the operation
Age
From **8 years** old to **55 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization of patients is done in a simple way. In this way, the samples are placed in sealed envelopes by number and each patient is asked to choose one envelope from the set of envelopes at the time of visit. Depending on whether the number is odd or even, the patient is assigned to one of the intervention or control groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
The method of blinding will be such that the patients and the person collecting the data are unaware of the type of drug used. The drugs are prepared by one of the operating room personnel who is not in the course of the study in similar and coded syringes and given to the project manager for injection. Also, the person collecting the data is not aware of the type of drug injected to the patients
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
Hezarjerib street
City
Isfahan
Province
Isfehan
Postal code
8434193474
Approval date
2023-04-17, 1402/01/28
Ethics committee reference number
IR.MUI.MED.REC.1402.048

Health conditions studied

1

Description of health condition studied
Septorhinoplasty surgery
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity of post operative pain
Timepoint
Every 6 hours after the operationuntil 24 hours
Method of measurement
Vigual Analog Scale

2

Description
Intensity of post operativenausea
Timepoint
Every 6 hours after the operation until 24 hours
Method of measurement

Vigual Analog Scale

3

Description
Restlesness after surgery
Timepoint
During recovery and every 6 hours after operation up to 24 hours
Method of measurement
Richmind scale

Secondary outcomes

1

Description
Blood pressure
Timepoint
Every 15 minutes during operation and recovery
Method of measurement
Sphygmomanometer

2

Description
Heart bit
Timepoint
Every 15 minutes during operation and recovery
Method of measurement
Pulse oximeter made by MIVA company, Iran

3

Description
Blood oxygen saturation
Timepoint
Every 15 minutes during operation and recovery
Method of measurement
Pulse oximeter

Intervention groups

1

Description
Intervention group: receiving 0.1 mg/kg dexamethasone as intravenous infusion
Category
Prevention

2

Description
Control group: recipient of normal saline with the same volume as the intervention group
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra hospital
Full name of responsible person
Seyed Amir Mohammad Taravati
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Sofeh street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Gholamreza Askari
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan 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
Seyed amirmohamad Taravati

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

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Position
Professor

Latest degree
Specialist

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Anesthesiology

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Person responsible for updating data

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StatisticalConsultant

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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
The plan belongs to the government organization and it is not possible to share it.

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