Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of pharyngeal packs during septorhinoplasty surgery on post operative sore throat and nausea and vomiting

Protocol summary

Summary

Purpose: Effect of pharyngeal packs during septorhinoplasty surgery on post operative sore throat and nausea and vomiting. Single-center randomized, Double blind. The minimum sample size for this study was estimated to be 90. The sample size for this study was estimated to be at least 90 Based on a sample size of at least 80% power to test Chi-Square and were calculated using statistical software Ncss and PASS. (P<0.05) was considered significant. Inclusion criteria: All ASAII-I patients candid septorhinoplasty after regional ethical committee approval and written informed consent to participate in the study. Exclusion criteria: history of motion sickness; common cold with sore throat; consumption of analgesics in the past 48 hours; a history of substance abuse and smoking; difficult intubation and repeat laryngoscopy. Intervention: group(A), input pharyngeal pack after anesthesia, group(B): without pharyngeal pack. Primary outcome: sore throat. Secondary outcome: nausea and vomiting. Septorhinoplasty surgery patients were randomly divided into two groups A (with pharyngeal packing) and B (without pharyngeal pack). At the end of surgery pharyngeal pack is withdrawn from the patient's mouth in group A in the operating room. Surgeons, recovery nurses and statistics expert do not know the patient group. The sore throat in VAS (Visual Analog Scale) from 0 to 10 and nausea and vomiting (with or without) recorded 0 , 2 , 6 and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013011012094N1**
Registration date: **2013-05-27, 1392/03/06**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2013-05-27, 1392/03/06

Registrant information

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Majid Razavi
Name of organization / entity
Mashhad University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research, Mashhad University of Medical Sciences

Expected recruitment start date

2013-03-10, 1391/12/20

Expected recruitment end date

2013-07-11, 1392/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of pharyngeal packs during septorhinoplasty surgery on post operative sore throat and nausea and vomiting

Public title

Pharyngeal packs during surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: after regional ethical committee approval and written informed consent to participate in the study, all ASAI-II patients candid septorhinoplasty. Exclusion criteria: history of motion sickness; common cold with sore throat; consumption of analgesics in the past 48 hours; a history of substance abuse and smoking; difficult intubation and repeat laryngoscopy

Age

No age limit

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

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Vice Chancellor for Research, Mashhad University of Medical Sciences, Ghoreishi apartment, Daneshgah st, Mashhad

City

Mashhad

Postal code

Approval date

2012-11-05, 1391/08/15

Ethics committee reference number

511/3011

Health conditions studied

1

Description of health condition studied

septorhynoplasty

ICD-10 code

J34.2

ICD-10 code description

Deviated nasal septum

Primary outcomes

1

Description

Nausea & Vomiting

Timepoint

Post operative times:0 (recovery), 2 , 6 and 24 h

Method of measurement

Nausea: No or Yes (mild or severe), vomiting: Yes or No

2

Description

Sore throat

Timepoint

Post operative times:0 (recovery), 2 , 6 and 24 h

Method of measurement

Visual analog scale(VAS): Pain from 0=no pain to 10=sever pain

Secondary outcomes

1

Description

Duration of surgery

Timepoint

Beginning of anesthesia until extubation

Method of measurement

Hour

2

Description

Concomitant disease

Timepoint

Questionnaire preoperatively

Method of measurement

Patient history

3

Description

Receiving narcotic

Timepoint

Postoperative time

Method of measurement

The number of narcotic injection. Recorded in the questionnaire

Intervention groups

1

Description

Intervention group A: after induction of anesthesia, a

simple cotton gauze (16-layer) put in pharyngeal space by anesthesiologist.

Category

Prevention

2

Description

Intervention group B: without pharyngeal pack

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Dr Majid Razavi

Street address

Department of Anesthesia, Imam Reza Hospital, Ibne Sina Street, Mashhad

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research, Mashhad University of Medical Sciences

Full name of responsible person

Dr Mohsen Tafaghodi

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City

Mashhad

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, Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Dr Majid Razavi

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