

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparison of nasal packing versus septal stitches on airway complications during recovery from anesthesia

Protocol summary

Study aim

The objective of the study is to compare the incidence of airway related complications when using nasal packing versus septal stitch post-operatively in patients presenting for elective septoplasty for deviated nasal septum (DNS)

Design

A randomised controlled trial ; single study center with two interventional groups carried out from June 23 to Dec 23 , with sample size of 110 individuals in each group.

Settings and conduct

The study was conducted in Anesthesia department of combined military hospital rawalpindi, with randomized controlled method, non blind. The sampling was done by non probability consecutive sampling via lottery method and resident o duty marked the groups with X and Y chits. Patients of group marked with X chits were allocated septal stich group and patients with group marked Y chit were allocated nasal packing group.

Participants/Inclusion and exclusion criteria

The inclusion criteria included all patients >18 years presenting for pre-anesthesia assessment for elective nasal surgeries requiring nasal packing/septal stitch post-operatively. The exclusion criteria included patients < 18 years, pregnancy, previous history of septoplasty, patients with coagulation disorders, patients with advanced cardiac, respiratory, or metastatic disease, patients with concomitant nasal surgery including turbinatectomy etc. and patients unwilling to be included in the study or lost to follow-up.

Intervention groups

The patients were randomized into two groups of 110 patients each. Group N (n=110) to receive nasal packing and Group S (n=110) to receive septal sutures.

Main outcome variables

Main variables were followings 1. Time from recovery room to discharge 2. Median pain scores in recovery 3. Mean dose of analgesia post procedure in recovery room

before discharge 4. Laryngospasm 5. Hypoxia 6. Bleeding 7. Headache 8. Sleep disturbances

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240121060756N1**

Registration date: **2024-06-13, 1403/03/24**

Registration timing: **retrospective**

Last update: **2024-06-13, 1403/03/24**

Update count: **0**

Registration date

2024-06-13, 1403/03/24

Registrant information

Name

Muhammad Asif Hayat

Name of organization / entity

Combined military hospital rawalpindi

Country

Pakistan

Phone

+92 301 3171974

Email address

asifhayat577@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-06-10, 1402/03/20

Expected recruitment end date

2023-12-10, 1402/09/19

Actual recruitment start date

2023-06-15, 1402/03/25

Actual recruitment end date

2023-12-15, 1402/09/24
Trial completion date
 2023-12-15, 1402/09/24

Scientific title
 Comparison of nasal packing versus septal stitches on airway complications during recovery from anesthesia

Public title
 Benefits of septal stitches over nasal packing during recovery from general anesthesia

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Included all patients >18 years presenting for pre-anesthesia assessment for elective nasal surgeries requiring nasal packing/septal stitch post-operatively.
Exclusion criteria:
 Included patients < 18 years, pregnancy, previous history of septoplasty, patients with coagulation disorders, patients with advanced cardiac, respiratory, or metastatic disease, patients with concomitant nasal surgery including turbinectomy etc. and patients unwilling to be included in the study or lost to follow-up. Pregnant patients Previously history of septoplasty Coagulation disorders Cardiac diseases Respiratory diseases Unwilling for study

Age
 From **18 years** old

Gender
 Both

Phase
 2

Groups that have been masked
No information

Sample size
 Target sample size: **110**
 Actual sample size reached: **110**

Randomization (investigator's opinion)
 Randomized

Randomization description
 Simple Randomisation in both groups was done using lottery method. The unit of randomization was individual. At the day of surgery, before going to the operating room, all patients were asked to select envelopes prepared by a resident Anesthetist marked X and Y. Allocation concealment from the resident was done and only the consultant in the operating room was aware that patients in X were to undergo septal stitch and Y to undergo nasal packing

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

CMH ethical review board

Street address

Tamiz uddin road Rawalpindi

City

Rawalpindi

Postal code

46000

Approval date

2023-01-01, 1401/10/11

Ethics committee reference number

ERB.549 ethical review board of combined military hospital rawalpindi

Health conditions studied

1

Description of health condition studied

Airways complications in nasal packing versus stiches

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Airways complications in bilateral nasal packing versus septal stitches during recovery from general anesthesia

Timepoint

6 hours from post anesthesia recovery unit

Method of measurement

Visual analogue score , pulse oximeter for saturation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Nasal packing group; vaseline soaked Nasal packing done during general anesthesia in septoplasty patients for mechanical to readjusted septum , to reduce bleeding .

Category

Treatment - Other

2

Description

Intervention group: Septal stitches group , quilted stitches applied to reduce incidence of airway complications, laryngospasm, decrease bleeding, hematoma formation, hypoxia, good recovery with decreased healing time .

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Combined military hospital

Full name of responsible person

Dr Muhammad Asif Hayat

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Tamizudin Road, rawalpindi

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Phone

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Email

Asifhayat577@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Combined military hospital

Full name of responsible person

Dr Ghulam Sabir

Street address

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Asifhayat577@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Combined military hospital

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

Combined military hospital

Full name of responsible person

Dr Muhammad Asif Hayat

Position

Post graduate resident anaesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Full name of responsible person

Dr Muhammad Asif Hayat

Position

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Latest degree

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Other areas of specialty/work

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Person responsible for updating data

Contact

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Combined military hospital

Full name of responsible person

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Position

Post graduate resident of anaesthesiology

Latest degree

Medical doctor

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data could be provided

When the data will become available and for how long

Data will be available for two years starting from July 2023 to July 2025

To whom data/document is available

Academic institutions

Under which criteria data/document could be used

Intervention studies being done on the same topic

From where data/document is obtainable

asifhayat577@gmail.com

What processes are involved for a request to access data/document

Can contact to email (asifhayat577@gmail.com) for detailed data .

Comments