

How throat packing impacts nasal surgery outcomes: A study on elective procedures

Submission date 18/11/2024	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 20/11/2024	Overall study status Completed	<input checked="" type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 20/11/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

This study aims to compare different methods of throat packing used during elective nasal surgeries. The goal is to see which method is most effective at reducing post-operative nausea and vomiting (PONV) and post-operative sore throat (POST).

Who can participate?

Patients aged 15-60 years who are undergoing elective nasal surgery under general anesthesia can participate in this study.

What does the study involve?

Participants will be randomly assigned to one of three groups: one group will receive oropharyngeal packing, another will receive nasopharyngeal packing, and the third group will not receive any packing. This packing is done before the surgery begins.

What are the possible benefits and risks of participating?

There are no significant risks, but there is a small chance that the packing could increase nausea, vomiting, or sore throat.

Where is the study run from?

The study is being conducted at King Abdulaziz University Hospital, King Saud University, in Riyadh, Saudi Arabia.

When is the study starting and how long is it expected to run for?

November 2015 to February 2019

Who is funding the study?

Investigator initiated and funded

Who is the main contact?

Dr Saad Alsaleh, alsaad@KSU.EDU.SA

Contact information

Type(s)

Public, Scientific, Principal investigator

Contact name

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Additional identifiers

Clinical Trials Information System (CTIS)

Nil known

ClinicalTrials.gov (NCT)

Nil known

Protocol serial number

E-15-1696

Study information

Scientific Title

Pharyngeal Packing Effects in Elective Nasal Surgeries: a randomized controlled double-blinded trial

Acronym

PENS

Study objectives

Pharyngeal packing (oropharyngeal and nasopharyngeal) offers no benefits when compared to no packing in terms of mitigating postoperative nausea and vomiting and postoperative sore throat.

Ethics approval required

Ethics approval required

Ethics approval(s)

approved 26/11/2015, College of Medicine Institutional Review Board (King Saud University, College of Medicine, Riyadh, 11472, Saudi Arabia; +966 11467001; kfaleh@ksu.edu.sa), ref: E-15-1696

Study design

Randomized controlled three-arm double-blinded study

Primary study design

Interventional

Study type(s)

Prevention

Health condition(s) or problem(s) studied

Prevention of postoperative nausea and vomiting and postoperative sore throat in elective nasal surgeries

Interventions

Using the sealed envelope method, patients undergoing elective nasal surgeries were randomly allocated to one of three study arms: nasopharyngeal, oropharyngeal, and no packing groups. The first arm will undergo oropharyngeal packing using a moist gauze pack positioned in the oropharynx by the anesthetist. The second arm will undergo nasopharyngeal packing by the operating surgeon, using a Merocel pack inserted into the nasopharynx and a saline injection to seal off the nasopharynx. The third arm will not undergo any packing.

Intervention Type

Procedure/Surgery

Primary outcome(s)

1. Postoperative nausea and vomiting is measured using the Rhodes nausea and vomiting score at 6 and 24 h postoperatively.
2. Postoperative sore throat pain is measured using a visual analogue scale (VAS) at 6 h, 24 h, and 10 days postoperatively.

Key secondary outcome(s)

There are no secondary outcome measures

Completion date

28/02/2019

Eligibility**Key inclusion criteria**

1. 15–60 years
2. Undergoing sinonasal surgery, including septoplasty, unilateral or bilateral functional endoscopic sinus surgery (FESS), inferior turbinoplasty, and open or closed rhinoplasty under general anesthesia (GA).

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

15 years

Upper age limit

60 years

Sex

All

Total final enrolment

99

Key exclusion criteria

1. Patients with documented difficulty in intubation
2. Patients with medical co-morbidities
3. Patients with pre-existing nausea and vomiting

Date of first enrolment

01/03/2018

Date of final enrolment

28/02/2019

Locations**Countries of recruitment**

Saudi Arabia

Study participating centre

King Abdulaziz University Hospital, King Saud University

King Abdulaziz Rd, Al Malaz

Riyadh

Saudi Arabia

12629

Sponsor information**Organisation**

King Saud University

ROR

<https://ror.org/02f81g417>

Funder(s)

Funder type

Other

Funder Name

Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be available upon request from Leen Alhadlaq (leenalhadlaq@gmail.com).

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Statistical Analysis Plan			20/11/2024	No	No