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

Submission date 18/11/2024	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 20/11/2024	**Overall study status** Completed	[X] Statistical analysis plan [_] Results
Last Edited 20/11/2024	**Condition category** Surgery	[_] Individual participant data [X] 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, alssaad@KSU.EDU.SA

Contact information

Type(s)
Public, Scientific, Principal Investigator

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Prevention

Participant information sheet
No participant information sheet available

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 measure
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.

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/11/2015

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

Age group
Mixed

Lower age limit
15 Years

Upper age limit
60 Years

Sex
Both

Target number of participants
78

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
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Sponsor information

Organisation
King Saud University

Sponsor details
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Sponsor type
University/education

Website
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ROR
https://ror.org/02f81g417

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Publication and dissemination plan
Planned publication in a peer-reviewed journal after retrospective registration is completed.

Intention to publish date

01/01/2025

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be available upon request form 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