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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 [_] 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

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

Primary study design
Interventional

Study design
Randomized controlled three-arm double-blinded study

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 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