

STUDY PROTOCOL SUMMARY FOR CLINICALTRIALS.GOV

Official Title: Efficacy of Quilting Suture Technique as Compared to Chain Suture in Patients Undergoing Septoplasty

NCT Number: To be assigned

Document Date: January 11, 2021

1. Study Overview

This is a two-arm, parallel-group randomized controlled trial designed to compare the efficacy and postoperative outcomes of quilting suture and chain suture techniques in patients undergoing septoplasty for symptomatic deviated nasal septum.

2. Study Design

Study Type	Interventional
Study Model	Parallel Assignment
Allocation	Randomized
Number of Arms	2
Planned Enrollment	84 participants
Allocation Ratio	1:1
Masking	None (Open Label)
Primary Purpose	Treatment

3. Condition

Deviated Nasal Septum

4. Interventions and Arms

Arm 1 – Quilting Suture: Participants will undergo septoplasty with closure and stabilization of the nasal septal flaps using the quilting suture technique. A 3/0 synthetic absorbable Vicryl continuous single suture will be used.

Arm 2 – Chain Suture: Participants will undergo septoplasty with closure and stabilization of the nasal septal flaps using the chain suture technique. A 3/0 synthetic absorbable Vicryl suture will be used.

5. Eligibility Criteria

Inclusion Criteria:

- Patients older than 15 years.
- Patients with symptoms of deviated nasal septum causing difficulty in nasal breathing.
- Patients having traumatic and caudal septal dislocation.

Exclusion Criteria:

- Patients having other medical issues such as leprosy, syphilis, tuberculosis, or blood dyscrasias.
- History of drug sniffing such as cocaine use.
- Previous history of nasal or septal surgery.
- Patients unfit for general anesthesia.

6. Randomization

After fulfilling the eligibility criteria and providing informed written consent, participants will be randomized into two groups using a lottery method. Group A will receive quilting sutures and Group B will receive chain sutures. Each group will include 42 participants.

7. Primary Outcome Measure

Duration of Suture Placement

Duration will be measured in seconds from placement of the first suture to completion of the last suture and compared between the quilting suture and chain suture groups.

Time Frame: During the surgical procedure.

8. Secondary Outcome Measures

Postoperative Pain

Assessed using the Visual Analog Scale (VAS).

Time Frame: Postoperative days 1, 2, and 3.

Postoperative Bleeding

Assessed using the predefined bleeding scale.

Time Frame: Immediately after surgery and during postoperative days 2 and 3.

Septal Hematoma

Presence or absence of postoperative septal hematoma will be assessed clinically.

Time Frame: Postoperative follow-up.

Adhesions/Synechiae Formation

Assessed by anterior rhinoscopic examination.

Time Frame: Postoperative day 15 and 1 month.

9. Statistical Analysis

Data will be entered and analyzed using SPSS version 26. Quantitative variables such as age, duration of surgery, and pain score will be presented as mean $\pm$ standard deviation. Qualitative variables will be presented as frequencies and percentages. Chi-square testing will be used for qualitative outcomes and t-test for quantitative outcomes. A P value of less than 0.05 will be considered statistically significant.

10. IPD Sharing

Individual participant data will not be shared because the study is being conducted for academic research purposes and individual-level data contain participant information that will not be made publicly available. Only aggregate study results will be reported.

Prepared from the study protocol provided for ClinicalTrials.gov registration. The document date above reflects the reported IRB/ASRB approval date of January 11, 2021.