

**The Effectiveness of Nasal Corticosteroids versus  
Placebo in Nasal Obstruction in Patients with Severe  
Nasal Septal Deviation**

**NCT02877485**

**April 13, 2016**

## Study Protocol

**Background:** Nasal septal deviation is a common cause of nasal obstruction, a symptom that can have a significant effect on a patient's quality of life. Insurance companies often require patients to try a  $\geq 6$  weeks treatment course with nasal steroids prior to covering nasal surgery. This is true even in cases of physician-documented severe or extreme anatomic nasal obstruction that have low likelihood of responding to medical therapy.

**Purpose:** This study will seek to determine if there is any benefit of intranasal steroids in decreasing nasal obstruction in patients with severe or extreme septal deviation compared to placebo therapy with intranasal saline spray.

**Study Population:** Individuals who are over the age of 18 with severe or extreme nasal septal deviation.

*Exclusion Criteria:* Intranasal steroid use within the last three months; current systemic steroid use; prior septal surgery; individuals who are pregnant or actively breastfeeding

**Study Design:** Randomized, double blind controlled crossover trial

**Sample size :** To detect a 20% difference in NOSE scores with 80% power and a 2-sided alpha level of 0.05 required 20 participants per study group, for a total of 40 participants.

**Statistical Analysis:** Statistical analyses were performed using IBM SPSS version 26 (IBM Corp., Armonk, NY, USA).

- 1) Independent t-tests will be used to assess differences in mean NOSE scores when comparing the two study groups,  $p < 0.05$  deemed statistically significant.
- 2) Paired t-tests were used to assess differences in mean NOSE scores after saline use, steroid use, and at various post-operative time points compared to the patient's own baseline NOSE score.

**Methods:** *Please see attached page for flow chart of the study protocol*

### STUDY DESIGN FLOWCHART:

Nasal Obstruction Symptom Evaluation (NOSE) Questionnaire and  
Physical Exam

