

**OFFICIAL TITLE OF THE STUDY :**

EFFECT OF OPTIC NERVE DIAMETER IN TYMPANOPLASTY  
SURGERY PERFORMED IN LATERAL HEAD POSITION UNDER  
GENERAL ANESTHESIA

NCT number (not available)

**Document Date:** 2020-01-12

## **RESEARCH PROTOCOL**

### **Official Title:**

EFFECT OF OPTIC NERVE DIAMETER IN TYMPANOPLASTY SURGERY PERFORMED IN LATERAL HEAD POSITION UNDER GENERAL ANESTHESIA

### **Research basis and rationale:**

Ultrasonography for optic nerve diameter (ONSD) measurement is a non-invasive, rapid, and easily applicable method for diagnosing intracranial pressure changes. In tympanoplasty surgery cases, the head and neck remain in a lateral position, and venous return can sometimes be compressed in the surgical field due to the procedure

### **Research objective:**

The aim of this study is to determine the effect of lateral head position and variables such as demographic data and surgical duration on the increase in intracranial pressure.

### **Research methodology:**

Patients over 18 years of age with ASA I and II who were to undergo tympanoplasty surgery in lateral head and neck position under general anesthesia (GA) were included. Patients' perioperative vital signs (arterial blood pressure, heart rate, sPO<sub>2</sub>, and EtCO<sub>2</sub>) were monitored routinely in the operating room. Demographic data (age, gender, weight, height), surgical duration, and perioperative complications were also recorded. Anesthesia was administered with propofol 2-4 mg/kg, rocuronium 0.6 mg/kg, and fentanyl 1-2 mcg/kg for induction, and sevoflurane for maintenance. Following intubation, ONSD measurements were taken in three time intervals by the anesthesiologist: transverse and sagittal planes. Both ONSDs were recorded by ultrasound at T1: 5 min in supine position, T2: end of the procedure with head in lateral position, and T3: supine position before extubation. Postoperative headache and neck pain were questioned upon awakening, and at 1, 6, and 24 hours.

### **Statistical methodology:**

Data were analyzed using Jamovi software (version 2.6.24). Descriptive statistics are presented as mean  $\pm$  standard deviation (SD) for continuous variables and as frequencies and percentages for categorical variables.

For the primary outcome, optic nerve sheath diameter (ONSD) measurements obtained at three time points (T1: post-intubation, T2: lateral head position during surgery, T3: supine position before extubation) were analyzed using repeated measures analysis of variance (ANOVA). Post-hoc pairwise comparisons were conducted to identify specific differences between time points, with

Bonferroni correction applied for multiple comparisons.

To investigate factors affecting ONSD changes, the relationship between surgical duration and temporal ONSD variations was examined. Patient age, body mass index (BMI), and surgical side (right vs. left ear) were also evaluated for their effects on ONSD.

To compare ONSD changes between ipsilateral and contralateral eyes relative to the surgical side, a mixed-design ANOVA was performed with Time (3 levels: T1, T2, T3) and Eye (2 levels: right, left) as within-subjects factors and Surgical Side (2 levels: right ear, left ear) as a between-subjects factor.

Statistical significance was set at  $p < 0.05$  for all analyses.

An a priori power analysis was performed using G\*Power (version 3.1.9.7) for a repeated measures ANOVA with time as the within-subject factor (three measurements). Effect size estimation was based on pilot data (mean ONSD values: 5.27, 5.57, and 5.40 mm), yielding an estimated effect size of  $f = 0.45$ . Assuming an  $\alpha$  level of 0.05, a power of 95%, three repeated measurements, and a correlation among repeated measures of 0.5, the minimum required sample size was calculated as 18 patients.