Statistical Analysis Plan

Official Title : Comparison of Operating Conditions, Postoperative Recovery and Overall Satisfaction Between Deep and Restricted Neuromuscular Blockade for Spinal Surgery Under General Anesthesia

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Statistical Analysis Plan	
1.Statistical Analysis Plan and Sample Size Justification	*** Statistical Analysis Plan** Statistical analyses will be performed using SPSS software (SPSS version 20.0, IBM, Chicago, IL, USA). Student's t-test or Mann–Whitney U-test will be used to compare continuous data including the mean values of the peak inspiratory pressure, the pressure of back muscle retractor and recovery time between the groups. Though measurement timepoints of peak inspiratory pressure and pressure of back muscle retractor are multiple, the mean value of each timepoint will be calculated and the mean value of each group will be analysed by Student's t-test. The normal distribution of the continuous data will be first evaluated using the Shapiro-Wilk test ($P > 0.05$). The normally distributed data will be analysed using the Student's t-test, and the abnormally distributed data will be analysed using the Mann–Whitney U-test. Ordinal variables including, the degree of bleeding of each patient scaled by surgeons, assessed using a 6-point scale and overall satisfaction of surgeons, assessed using numerical rating scale (NRS; 1-10) will be compared using the Mann–Whitney U-test. Categorical variables such as the muscle tone of each patient scaled by surgeons, assessed using a 3-point scale, the number of body movements during the surgery and the incidence of adverse events between the groups will be compared using a chi-squared test (or Fisher's exact test). The data will be expressed as the mean ± standard deviation, median (25; 75 quartiles), or number of patients (%). P-values will be reported as two-tailed values and a P-value < 0.05 will be considered statistically significant. *** Sample size calculation** Primary endpoint in this study is mean value of peak inspiratory pressure during the surgery. The sample size calculation was based on the results of a pilot study with 10 cases in each group. In the pilot study, peak inspiratory pressure (mean ± standard deviation) was 18.8 ± 2.9 cmH_2O in Group DB and 20.7 ± 3.0 cmH_2O in Group RB, respectively. Therefore, the effect size of 2-groups was 0.64. On the assumption that the allocation ratio of 2-groups was 1, a sample size of 39 patients was selected for each group, calculated by Student's t-test, two-sided test, a level of significance of 0.05 and a power of 0.8. We estimated a 15% drop-out, resulting in the final enrolment of 45 patients in each group (total, 90 patients).