

ISRCTN registry – submission reference number 43858

Statistical analysis plan

Sample size

Necessary sample size was determined based on the primary objective of comparing blood loss and surgery duration (namely a t-test for independent samples). The analysis used a power of 0.9, alpha level of 0.05, two-sided alternative, and Cohen's d, effect size of 0.9. The calculation indicated a minimum of 27 patients in each group. To account for potential dropouts, a 15% coefficient was applied, resulting in a final required sample size of 31 patients in each group.

The sample size was determined with the R 4.2.2 package "pwr" version 1.3

Randomization was single-blind and performed with the R 4.2.2 package "blockrand" version 1.5.

Data analysis

Categorical variables were described by the observed frequencies (i.e., counts) and their corresponding percentages; The Chi-square test was applied for statistical significance (either asymptotic, or Monte-Carlo simulation based on 10000 samples).

Normality of numerical variables was tested with Kolmogorov-Smirnov statistical test; their descriptive statistics comprised the mean \pm standard deviation and (minimum–maximum) interval, irrespective of their distribution. To compare normally distributed series of values, the t-test for independent groups was applied for the means, and Levene's test for the variances. To compare non-normal numerical data across two groups, a non-parametric Mann-Whitney U-test was applied.

The statistical analysis was conducted at a 95% level of confidence (i.e. 5% level of statistical significance). All reported probability values were two-tailed, and statistical significance was explicitly marked.

Data were analyzed with the statistical software IBM SPSS version 20.0 and R version 4.2.2.