

STATISTICAL ANALYSIS PLAN

COLOROBOT-ELX 24

1. Statistical analysis plan

The data obtained from each patient will be entered into a database and SPSS version 29.0 software will be used for statistical analysis. In the descriptive analysis, the appropriate estimators will be used depending on the type of variables: means or medians, standard deviation (SD) or ranges, for quantitative variables, and percentages (%) for qualitative variables. In the bivariate analysis, the Chi-square test will be used for qualitative variables, and for quantitative variables the Student's t test if the distribution is normal and the Mann-Whitney U test when such normality cannot be assumed (the normal distribution of the variables will be analyzed using the Kolmogorov-Smirnov test). In all estimates, 95% confidence intervals will be calculated and a p value less than 0.05 will be considered significant.

2. Sample size

Regarding the sample size, it has been seen that the prevalence of all the indicators that require a larger sample size is 25% for colon cancer infection, (according to the quality criteria of the Spanish Society of Coloproctology), with a statistical power of 80% and a confidence level of 95%, 28 patients are required. In addition, 10% is assumed for loss to follow-up; in the end, a minimum sample size of 30 patients is required. Knowing that the prevalence of the rectal cancer infection indicator is 23% (according to the quality criteria of the Spanish Society of Coloproctology), which requires 24 patients, the previously mentioned sample size of 30 patients will be increased to 56 patients assuming both losses to follow-up.