

COVER PAGE

Vaginal Mesh Surgery Versus Robotic-assisted Abdominal Mesh Surgery in the Treatment of Apical Prolapse - Prospective Randomized Non-inferiority Study

NCT ID: not yet assigned

Protocol ID 7.815.545

Document Date: 09-03-2025

Sample Size Calculation and Statistical Analysis Plan

The sample size was calculated to assess the non-inferiority of the vaginal approach compared with the abdominal approach. Assuming an objective cure rate (stage 0 or I) of 90% for the abdominal group and 80% for the vaginal group, with a two-sided significance level of $p < 0.05$ and an anticipated loss to follow-up of up to 10% in each group, a minimum of 43 participants per arm (total of 86 patients) was required. The calculation was based on detecting a non-inferiority margin considered clinically acceptable for the primary outcome.

For statistical analysis, quantitative variables, whether continuous or ordinal, will be summarized using measures of central tendency (means or medians) and their corresponding measures of dispersion (standard deviations or interquartile ranges). Qualitative (categorical) variables will be presented as absolute frequencies and percentages.

Comparisons of continuous variables will be performed using Student's t-test or the Mann–Whitney U test, as appropriate. Categorical variables will be compared using the chi-square test or its applicable variants.

The magnitude of associations between categorical variables will be expressed as Odds Ratios (ORs), accompanied by 95% confidence intervals to indicate the precision of estimates.

A two-sided p-value < 0.05 will be considered statistically significant.