Statistical Analysis Plan

Title: Drainage Fluid Biomarkers and Postoperative Gastrointestinal Dysfunction in Laparoscopic Colorectal Surgery. A Monocentric Prospective Observational Study

NCT number: NA yet

Study data: 2024.01.08

1.Study Design

Study Type: Prospective single-central observational study
Observational Study Model: Case-Only
Study Start: February 18, 2024
Estimated completion date: October 1, 2024

2. Methods for generating random sequence assignments

N/A.

3. Blindness and blinding

N/A.

4. Sample size calculation

In a previously published study conducted at our institution, the incidence of postoperative prolonged ileal obstruction (PPOI) was approximately 38.0% (1), a figure we approximated to be equivalent to the incidence of postoperative gastric dysfunction (POGD). The ratio of the POGD group to the non-POGD group was approximately 3:5. Sample sizes were determined based on the primary study endpoints, and the mean lactate dehydrogenase (LDH) in the POGD group on postoperative day 1 (POD.1) was (1406.5±70), as per the pretest results. The mean LDH for the non-POGD group was 1210±343.Utilizing a one-sided, two-sample unequal-variance t-test with a power of 0.8 and an α-value of 0.05, calculated using PASS2021 (NCSS, USA), the required number of cases was determined to be 45. The Neutrophil-to-Lymphocyte Ratio (NLR) value for the POD.1 POGD group was (156.3±14.7), while the mean NLR value for the non-POGD group was (39.4±37.5). The calculated sample size for this comparison was 8 cases, with a maximum sample size of 45 cases. In this study, age and TNM stage were primarily controlled as confounders. Assuming that 5 event samples are required to control for each variable, an additional sample of 14 cases is necessary,

bringing the total required sample size to 59 cases. Considering a 5% dropout rate, the final recruitment requirement is 63 cases.

5. Statistical analysis

Statistical analyses were performed by SPSS statistical software v.17.0 (SPSS Inc., Chicago, IL, USA) and R Language v.4.0.3 (R Foundation for Statistical Computing, Vienna, Austria). Measures that met normality were expressed as mean ± standard deviation were analyzed using the t-test, and measures that did not meet normality were expressed as median and interquartile range and analyzed using the Mann-Whitney rank sum test. The cutoff value was selected by the use of the Youden index35 (sensitivity + specificity − 1), and the count data were expressed as number of cases and percentages and analyzed using chi-square test. Predictors of postoperative complications and POGD were studied by univariate and multivariate logistic regression (LR). The diagnostic performance of biomarkers was assessed by receiver operator curve (ROC) analysis.

6. Data collection and management

Simultaneous recording of electronic data and paper report forms.

7.Data Management Programmer

Paper files were sealed one at a time in the order of entry into the group, opened and recorded during interim analysis and data analysis, and stored and backed up in a timely manner. Regularly updated on clinicaltrials.gov.

8.Reference

1. Fan ZQ, Chen Y, Fu XA, Yin HT, Li JS, Wang WS, et al. Nomogram for predicting prolonged postoperative ileus in colorectal cancer based on age and inflammatory markers. Biomark Med. 2023 Nov;17(22):921–33.