

Statistic Analysis Plan

Title of study	Neoadjuvant chemotherapy combined with camrelizumab and apatinib in patients with locally advanced colon cancer: a single-arm, prospective study
NCT number	NCT04625803
Institution	The First Affiliated Hospital, Zhejiang University School of Medicine
major investigators	Weijia Fang Xiangming Xu
Protocol No.	MA-CRC-II-004
Version	1.3
Version Date:	07 November 2021

1.sample size

This was a single-arm study, and no randomization was used. To determine the sample size, we used the Simon 2-stage optimum design with a unilateral alpha of 0.05 to achieve a power of 0.8, and the pathological response rate (TRG 2-4) was expected to increase from 22.5% to 40%. Considering a 10% shedding rate, it was estimated that 64 patients needed to be enrolled.

2. Subject Distribution

Descriptive analysis of subject distribution, including but not limited to enrollment, withdrawal, and major protocol violations. The reasons for screening failure and the reasons for quitting the test were summarized.

3. Demographic and Other Disease Characteristics

Descriptive statistics were performed on sociodemographic characteristics and other disease characteristics. Sociodemographic characteristics include age, sex, etc. Other characteristics include tumor history and past medical history.

4. Analysis of Primary Study Endpoint

The primary endpoint of this study is pathological response rate, which will be aggregated and its 95%CI.

5. Secondary Study Endpoint Analysis

For the temporal event data (DFS, OS) in the secondary endpoints, Kaplan-Meier was used to estimate the median value, estimate the 95%CI of the median DFS/OS, plot a survival curve, and estimate the 2-year disease-free survival and its 95%CI.

Statistical rates and 95%CI were pooled for binary data in secondary endpoints (tumor pathological downphase rate, pCR rate, and R0 removal rate).

6. Safety Analysis

All the statistical analyses were performed using SPSS Statistics 26 (IBM, Armonk, NY, USA). Continuous variables with parametric distributions were evaluated using t tests. Categorical variables were evaluated using the chi-square test (or Fisher's exact test where appropriate). All the statistical tests were two-sided, and the significance threshold for all the P values was 0.05. Graphs were generated using GraphPad Prism (version 10.1.1).