

Identifiers: NCT03453164 Unique Protocol ID: RK29040
Brief Title: Checkpoint Inhibitor and Radiotherapy for Recurrent Gastric Cancer (CIRCUIT)
Date: 15th Jan, 2020

Statistical Analysis Plan

1. Demographics and Baseline Characteristics

Demographic and baseline disease characteristics will be summarized using descriptive statistics for all treated patients.

2. Efficacy Analysis

The primary endpoint for this trial is a proportion of disease control, which is defined as the total number of patients with CR/PR/SD divided by the number of all treated patients. A corresponding one-side 95% confidence interval will be provided using the Clopper-Pearson method. The null hypothesis, i.e. a proportion of disease control is equal or less than 20%, will be evaluated using the binomial test.

The secondary endpoints include the median overall survival (OS) and a proportion of local control. OS is defined as the time from start of radiotherapy until death from any cause. An estimate of median OS will be calculated using the Kaplan-Meier method, along with corresponding 95% confidence interval using the Brookmeyer-Crowley method. A proportion of local control is defined as the total number of patients with locally CR/PR/SD divided by the number of all treated patients. A corresponding one-side 95% confidence interval will be provided using the Clopper-Pearson method.

3. Safety analysis

All adverse events will be summarized without regard to causal relationships to the study treatment. The worst toxicity grades based on CTCAE ver4.0 per subject will be tabulated for adverse events and toxicities. Any serious adverse events will be described in detail.