The Effectiveness and Mechanism Study of Auricular Needling in Treating Cancer Induced Anorexia (Clinical Research) Statistical Analysis Plan

2016.05.01

Statistical analysis

1 Statistical analysis data set

① Full Analysis Set (FAS)

is the ideal set of subjects that is as close as possible to the principle of intentional analysis (the primary analysis is to include all randomized subjects), and which is derived from the smallest and reasonably methodologically sound elimination of all randomized subjects. Estimates of missing values for the primary variables were carried forward (carry-forward) to the point where trial data were missing using the Last Observation Carry Forward (LOCF) method, with the number of subjects evaluating efficacy at endpoint remaining the same for each group as at the start of the trial. the FAS population was used for the analysis of the primary and secondary efficacy measures.

② Per Protocol Set (PPS)

Per Protocol Set (PPS): All cases that comply with the trial protocol, use 80%-120% of the medication, have good adherence, do not use banned drugs during the trial, and complete the CRF requirements.The PPS cohort is used for the analysis of primary and secondary efficacy indicators.

(iii) Safety Set (SS)

The safety set (SS) is a randomized group of patients who have used the study drug at least once and have at least 1 follow-up visit. The safety set is the main population for the safety evaluation of this study.

2 Statistical analysis plan

Statistical analyses will be calculated using SAS 9.2 statistical analysis software.

The primary validity analysis dataset will be FAS, and PPS will also be analyzed.

All statistical tests will be two-sided, and a p-value of less than or equal to 0.05 will be considered a statistically

The differences tested were considered statistically significant.

Measures for each visit in the different treatment groups were described statistically as mean ± standard deviation. Comparisons were made with the baseline values at the time of enrollment using the paired t-test. The paired t-test was used to compare pre- and post-treatment differences within groups. Changes before and after treatment in each group were compared using analysis of variance (ANOVA). The count data of each visit of different treatment groups were statistically described by frequency counts (constitutive ratio). Changes before and after treatment in each group were analyzed using the X^2 test or nonparametric The X^2 test or non-parametric test was used.

Shedding analysis: The X^2 test will be used to compare the total shedding rate and the shedding due to adverse events in each group.

Balanced analysis of baseline values: ANOVA or X^2 test will be used to compare demographic data and other baseline indicators to measure how well balanced the two groups are. measure how well the two groups are balanced.

Effectiveness analysis: PPS and FAS were used to analyze the primary and secondary indicators; since this study is a multicenter clinical trial, the impact of central effects on the efficacy indicators should be considered in the analysis. Since this study is a multicenter clinical trial, the influence of center effect on the efficacy indexes should be considered in the analysis.

Safety analysis: the X2 test was used to compare the incidence of adverse events in the two groups, and the adverse events occurred in this trial were described in a list. Adverse events: the X2 test was used to compare the incidence of adverse events in the two groups, and the adverse events occurred in this trial were described in a list; the changes of normal/abnormal laboratory test results before and after the trial were analyzed, as well as the relationship between the abnormal changes and the test drug. Safety analysis: The X2 test was used to compare the incidence of adverse events in the two groups and to describe the adverse events in this trial.