Safety and Efficacy Evaluation of Remimazolam for Endoscopic Ultrasound-guided Fine Needle Aspiration/Biopsy

Unique protocol ID:EUS-FNA-2022-01

Date:2022-05-10

Statistical Analysis Plan

Sample size calculation

According to the existing literature, the estimated incidence of cardiopulmonary adverse events in the propofol group is about 19.5%, and the estimated incidence of cardiopulmonary adverse events in the remimazolam group is about 4.0%; Set the two-sided α=0.05, the power is 95%, and the sample size of each group is 110 calculated by PASS15 software. Considering the 20% loss to follow-up rate, the total sample size of the test is 264.

General rules

Standard descriptive statistics were provided for binary and continuous variables using incidence frequency (%) and mean ± standard deviation. The Chi-square test was used to compare binary variables, and the two-sample t-test was used to compare continuous variables. Two-sided P-values were calculated and the significance was accepted at the 5% level. Logistic regression analysis was used to explore the risk factors of adverse events under different sedation regimens.

Demographics and baseline conditions

Demographics and baseline conditions will be analyzed in the Full Analysis Set and Per Protocol Set. All demographic variables and baseline characteristics would be summarized. Standard descriptive statistics were provided for binary and continuous variables using incidence frequency (%) and mean ± standard deviation.

Statistical Analysis Plan for outcome measurement

The incidence of cardiopulmonary adverse events, the incidence of other adverse events and the success rate of sedation would be compared between the two groups of patients; the curve of average heart rate, systolic blood pressure, diastolic blood pressure, pulse oxygen saturation and MOAA/S value of the two groups of patients at different time points would be recorded; The area under the curve of heart rate, systolic blood pressure, diastolic blood pressure, blood oxygen saturation and MOAA/S value within a fixed time interval would be compared, and the average heart rate, systolic blood pressure, diastolic blood pressure, pulse oxygen Saturation and MOAA/S scores would be used for multiple comparisons of repeated measures data. Logistic regression would be used to analyze the risk factors for the incidence of sedation cardiopulmonary adverse events.