Statistical Analysis Plan

Patients will be divided into control or intervention with center randomisation. Full Analysis Set (FAS): Analyzes all cases that were randomized into clinical trials. The shed data was estimated using the LOCF method. Per Protocol Set(PPS): Analysis of all cases that meet the test plan, good compliance, no banned drug use during the trial, and complete the contents of the CRF regulations. The efficacy analysis of this trial was simultaneously analyzed using the full analysis set and the compliance set. The entire analysis will be undertaken with "the intention-to-treat" principle, even though we have foreseen a"by protocol"analysis. only patients who have received at least the minimum established doses of PEAF treatment in the experimental arm will be evaluated.

The descriptive analysis will be performed using means and SDs for quantitative variables and absolute and relative frequencies for qualitative variables. To verify the homogeneity of both groups, χ^2 (Pearson or Fisher) and t-test will be used. To determine the benefit of our intervention, the clinical relevance indicators will be calculated: relative risk, absolute risk reduction, relative risk reduction, number needed to treat.

Specific analysis method:

1. Statistical descriptions were performed for the cases of rejection and shedding and for pretreatment data, Pearson χ^2 test was used for all-cause mortality within 28 and 90 days.
2. Pearson χ^2 test or exact probability calculation, t-test or analysis of variance and non-parametric test were performed for other outcomes.
3. the central effect CMH method was performed for the comparison of the clinical efficacy of the two groups,and the qualitative or ordinal variables are analyzed by using the GEE method.
4. A statistical description method was used for adverse reactions. Chi-square or Fisher exact test were used for the incidence of adverse reactions between groups.
5.Survival analysis: Cox survival curve; multivariate analysis: unconditional logistic regression;

All analyses will be performed with a significance of 5% and the associated CI of each relevant parameter will be calculated. The statistical software used will be IBM SPSS Statistics V.22.