Statistical analysis plan

1.Statistical software

Using STATA version 12.0 statistical software.

2. Special data processing

(1)Missing data: When a certain important data due to loss,miss follow-up, examination is happen, the LOCF method will be adopted to carry out the data and the secondary index will not be transferred.

(2)Outlier data: According to statistical and medical analysis, determine these data will be included or not. Sensitivity analysis was conducted for the outliers of the main targets, including two results consistent with those who did not outliers.

3. Selection of inspection level α and power of test β

（1）Difference test: With α=0.05 as the test standard, two-sided test was adopted, and the statistical methods, statistics and specific *P* values were given. $P \leqslant 0.05$ was considered statistically significant.

（2）Superiority test: Based on a power of 80%（β=0.2），α=0.025 was conducted for the one-sided test. The difference between the groups and the 95% confidence interval of the mRS score difference to the baseline values after treatment in the experimental group and the placebo group was calculated by the least square method. If the 95% confidence interval between the two groups was greater than 0, the experimental group can be thought to be superior to the placebo group, otherwise not.

4. Statistical expression

（1）The statistical report mainly expressed in form，which was self-evident.It had the title, the heading and the number of cases, the necessary remarks and the text of statistical results and the description of data results.

（2）Descriptive statistics: The measurement data is described by mean number, standard deviation, maximum value, minimum value, 95% confidence interval, median, Q1 and Q3.The enumeration data is described by frequency(constituent

ratio), and corresponding statistics and P value are calculated.

（3）Inferential statistics: Measurement data were compared between groups by analysis of variance or K-W rank-sum test according to the distribution pattern. Enumeration data were compared between groups by R*C Chi-squared test and Fisher exact test. The ranked data was tested by CMH. The main/important therapeutic effect index will use the baseline for the covariant, considering center, operation or not after injury for analysis of covariance.

5. Specific statistical analysis content

（1）Analysis of program implementation: a list was adopted to summarize the entry and completion of all and each central cases, and tabulate details and the data collation of those cases which are not meet the inclusion criteria, fall off, low compliance, against therapy and drug combination, interview time beyond window.

（2）Analysis the patient compliance and the drug combination during the trail.

（3）Condition of each analysis data set：Based on the analysis of the implementation of the program，determining the data imputation of each deviated test programme case. Summarize the cases of each analysis data sets, such as per-protocol set (PPS), full analysis set (FAS), safety set (SS).

（4）Baseline equalization analysis: Compare the baseline data of demographic data, vital signs and medical history related features.

（5）Analysis of curative effect index :

1）Compare the changes of mRS score to the baseline after using the drug in 2 days, followed up with 1 month and 6 months in the two groups. The main/important therapeutic effect index will use the baseline for the covariant, considering center, operation or not after injury for analysis of covariance.The covariance analysis was performed on the change of mRS score at baseline after 6 months of follow-up. The difference between the groups and the 95% confidence interval of the mRS score difference to the baseline values after treatment in the experimental group and the placebo group was calculated by the least square method. If the 95% confidence interval between the two groups was greater than 0, the experimental group can be

thought to be superior to the placebo group, otherwise not.

2）Compare the changes of cerebral hemorrhage amount to the baseline in the two groups.

3）Compare the changes of coagulation function, platelet level and GCS score to the baseline in the two groups.

4）Compare the number of days stayed in the ICU and the hospital in the two groups.

（6）Safety analysis:

Compare the incidence and classification rate of complications, adverse events and adverse reactions during the test in the two groups, and list the details of each adverse event,such as the detailed occurrence, outcome and the relationship with drugs.