

**Cyclophosphamide in the Treatment of
Panniculitis Associated Acquired Lipodystrophy Syndrome
With Type 1 Diabetes**

2019-04-09

Statistical Analysis Plan

1. Data collection:

Management team: The patients will be followed up by a fixed team of senior doctors and nursing staffs in our center, and all the data will be collected by the same team.

Data collection: Baseline data, such as gender, age, birth weight, medical history and family history, height, weight, fast plasma glucose, HbA1c, serum C-peptide concentration, serum lipid level, thickness of abdominal subcutaneous fat, subcutaneous fat biopsy results and so on will be collected when participants are diagnosed as panniculitis associated acquired lipodystrophy syndrome with type 1 diabetes. Average daily insulin dosage and insulin resistance will be evaluated before and after each cycle of treatment of cyclophosphamide. The follow-up will be carried out once every three months until 12 months after the completion of cyclophosphamide. In the event of dropouts or withdrawals, the reasons for each missing value will be recorded.

2. Statistical analysis

2.1 Data recording: Data will be recorded in a purpose designed Excel sheet by the researchers.

2.2 All paper data will be stored in locked filing cabinets and electronic data will be password protected.

2.3 A statistician who is not affiliated with this study will perform the statistical analyses.

2.4 The comparison of the glycometabolism and lipid metabolism between before and

after the cyclophosphamide treatment, including average daily insulin dosage, fast plasma glucose, HbA1c, serum C-peptide concentration, triglyceride level and thickness of abdominal subcutaneous fat will be analyzed using SPSS software. All of these indicators will be displayed as the mean, SD, and minimum and maximum values. One-way ANOVA will be used to examine significant differences for continuous variables. Two-sided p values less than 0.05 will be considered significant.