

Statistical analysis plan in 5th april 2022;

Investigators will randomly (the method of randomization will be explained in greater detail) divide the patients into two groups (1:1) either receive Omalizumab or placebo. The protocol specified study dosing of 75 to 600 mg by subcutaneous injection every 2 or 4 weeks, depending on the pretreatment serum total IgE level and body weight (Table 1). According to low prevalence of the disease, drug expensiveness and absence of similar study investigators forced to choose 15 patients in each group based on retrospectively review the number of patients referring to the hospital during one year. Indeed, in this study patients enter hard and leave easily because of inclusion and exclusion criteria. Sampling method is easy based on purpose. In this way, the investigator will be present at the time of the study and will begin sampling from accessible referral patients to obtain the total sample size.

-RANDOMIZATION METHOD:

One method of randomization is to use the RANDBETWEEN function in Excel. This function allows to investigators generate random numbers. To generate a random number in this study with a sample size of 30, between the two numbers 1 and 31, the function = Randbetween (1,31) is used. This function creates a column of random numbers between 1 and 31. The rand function selects numbers with equal probability in this interval, so the chance of selecting any number in this interval is equal to the other numbers. This means that each patient is assigned to enter one of two treatments, respectively. These data are 30 people who are randomly assigned to 2 treatments 1 and 2 (15 people in each group). The sample numbers in the first group and the second are as follows:

A: 15,7,6,29,23,13,10,25,12,1,4,17,26,20,11

B: 28,14,21,3,8,22,2,5,16,30,27,19,18,9,24

A or B could be contributed to both control and Omalizumab group.

The researcher who reviews the results is not aware of the group allocation.

All patients provided written informed consent. The study was conducted in accordance with the Declaration of Helsinki and all applicable laws and regulations.

For data analysis past 24weeks, the statistical package for social sciences (spss) version 23 software will use. Descriptive statistics including mean and standard deviation for quantitative variables and number (%) for qualitative variables will use to describe the data. Data analysis will performe using independent sample T-test and Chi-square test. The average of the parameters before and after, as well as the difference between the changes can be made with independent T test. The t-test is used to compare the mean of parameters in each of the two groups. The Chi-square test will use to compare the qualitative variables and qualities between the two groups.

The within-group means and between-group differences in absolute change from baseline to week 24 will be the estimated least squares means (LSMs) obtained by using a mixedeffect model with repeated measures with unstructured covariance matrix, adjusted for comorbid asthma/ aspirin sensitivity, time point per schedule of assessments, baseline outcome score, treatment by time point interaction, and baseline outcome score by time point interaction for NCS, UPSIT score, SNOT-22 score, and TNSS. P values will be derived from at test of difference in LSMs.

P value below 0.05 will be considered as significant.