A double-blind, parallel, randomized study: cetirizine oral solution (1mg / ml., 60 ml. / bottle) versus placebo in the treatment of children from 3 to 8 years old with perennial allergic rhinitis

Final Report

Head of department: Dr. M.H. Chang
Department of Pediatrics
National Taiwan University Hospital

Investigators: Dr. M. J. Tsai
Dr. H. L. Chen
Department of Pediatrics
National Taiwan University Hospital.
SYNOPSIS

TITLE
A double-blind, parallel, randomized study: cetirizine oral solution (1mg / ml., 60 ml. / bottle) versus placebo in the treatment of children from 3 to 8 years old with perennial allergic rhinitis

AIM OF THE TRIAL
The primary aim of the trial is to compare the efficacy and safety of 2.5 mg cetirizine oral solution and placebo administered twice daily for three weeks, on the improvement of the 3 to 8 years old children with perennial allergic rhinitis.

DESIGN
This study was designed to be a double-blind, placebo-controlled, parallel, randomized study.

STUDY POPULATION
Sixty children suffering from perennial rhinitis, 30 patients treated with 2.5 mg Cetirizine oral solution bid and 30 treated with placebo.

TREATMENTS
The intake of study medication will start on day 1 (the evening of visit 1), and last for three weeks. Everyday during treatment, in the morning and in the evening, subjects ought to take 5 ml / day of cetirizine oral solution or the same amount of placebo oral solution.

STATISTICAL METHOD
Efficacy variables analyzed included VAS assessment and five symptoms score evaluation. Statistical methods used to analyze the efficacy results were Mann-Whitney test, and Wilcoxon signed-rank test. Safety variable was adverse event incidence. Chi-square test was applied for the safety analyses. All test were performed by type I error of 0.05, two tailed.

STUDY SUBJECTS
A total of 60 patients were screened in this study; 30 were randomized to receive Cetirizine oral solution, and 30 received placebo. 27 of the 60 patients dropped out prematurely and 33 patients completed the study.
EFFICACY RESULTS
The efficacy variables were VAS and total symptom score. In the analysis of the valid patient population, the mean change of VAS from baseline to Visit3 was significantly greater with Cetirizine group than with placebo group (the mean increase is 29.4 and 9.0 in the Cetirizine and placebo groups, respectively, P<0.05). In addition, the decrease of the total symptom score in Cetirizine group is better than that in the placebo group. The results of intention to treat analysis confirm the finding and again show that Cetirizine treatment demonstrates more favorable efficacy profiles in this study.

SAFETY RESULTS
Ten patients report adverse events during the study period. The incidence of the adverse events between the two treatment groups was not statistically significant. The incidence of adverse events was in line with the known safety profiles of the agents and there were no unexpected or serious adverse events.

CONCLUSION
In this study of limited sample size, therapeutic efficacy and safety profile show that Cetirizine is a safe and effective treatment for allergic rhinitis in children aged 3-8 years.