Statistical method:

All analyses will performed with a commercially available software program (SPSS Statistical Software, version 11.5; SPSS, Inc, Chicago,Ill). The Shapiro-Wilks test will use to evaluate normality of the distributions collected. When variables were normally distributed, they were expressed as means (SDs); otherwise, they will express as medians and interquartile ranges (25th-75th percentiles). The χ^2 test will use for categorical variables and expressed as observation counts (in percentages). An ANOVA (or Mann-Whitney U depending on the normality of data) statistics will be used to compare means between both treatment groups for continuous variables. Bonferroni multiple comparison test will use to compared paired intervals (0-3, 0-6 months). All P values are 2-tailed; a P value of less than .05 are considered statistically significant.

Sample Size:

In one study OM-85 group showed 3 less RTIs compared with placebo over 12 months period. A sample size of 54 randomized patients (27 per group) will provide at least 80% power to detect a mean difference of at least 2.0 RTIs between the two groups assuming a SD of 2.55 and assuming a drop-rate of 20% after 6 months, total of 68 patients (34 per group) will recruit to the study.[1]

Reference:

María Dolores Gutiérrez-Tarango and Arturo Berber. Safety and Efficacy of Two Courses of OM-85 BV in the Prevention of Respiratory Tract Infections in Children During 12 Months. CHEST 2001; 119:1742–1748