STATISTICAL ANALYSIS PLAN

The baseline variables shall be described using descriptive statistics. Categorical variables will be described by percentages. Numerical variables will be described as mean (standard deviation) or median (1^{st}, 3^{rd} quartile), depending on distribution. Normality of distribution of numerical variables will be tested by Shapiro Wilk test and QQ plot.

The primary outcome variable is "definite or probable relapse" within 21 days after stopping antibiotics. Secondary outcome variables include individually definite and probable relapse within 21 days and 28 days after stopping antibiotics; definite and probable relapse within 28 days and 35 days after randomization; "definite or probable relapse" within 28 days and 35 days after randomization; secondary bacterial infections within 35 days after randomization and adverse events within 35 days after randomization. Analysis will be both per protocol as well as intention-to-treat, as this is a noninferiority trial.

As all the outcome variables are categorical, chi-square test with Yates correction or Fisher's Exact test, as applicable, will be used to compare the 2 groups.

Sub-group analysis has been planned for the following sub-groups: birth weight above 2000 gms versus less than or equal to 2000 g, those infected with gram positive organisms versus the rest and those with radiological pneumonia versus those without radiological pneumonia. A p-value for the test of interaction (Breslow-Day test) will be derived for the subgroup analyses.

Multi variable logistic regression analysis will be performed to determine the relationship between group membership (7-day course of antibiotics versus 14-day course of antibiotics) and the primary outcome after adjusting for the following baseline covariates: birth weight, age of neonate, infection with gram positive organisms, number of days by which clinical remission of sepsis achieved prior to randomization.

Mid-term analyses will be performed by an independent Data Safety Monitoring Board after either 50% of the expected primary outcomes occur or 50% of the sample size is recruited, whichever is earlier.

Data Safety Monitoring Board will monitor serious adverse events in the trial. O'Brien-Fleming's stopping criteria will be used for the primary outcome while Pocock's stopping rules will be used for serious adverse events.

Analysis shall be done using the statistical software packages SPSS version 22.