

Oral Probiotic Supplementation and Group B Streptococcus Rectovaginal Colonization in Pregnant Women: a Randomized Double-blind Placebo-controlled Trial

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Statistical analysis plan

Treatment group characteristics will be summarized and reported using numbers and percentages for categorical data, means and standard deviation for normally distributed data, and medians and interquartile ranges (IQR) for non-normally distributed data. Characteristics will be compared between the treatment groups using the standardized mean difference.

Binary study outcomes will be compared between treatment groups using the Cochran-Mantel-Haenszel test. Normally distributed outcomes will be compared using linear regression adjusting for site. Non-normally distributed outcomes will be compared using the van Elteren (vE) test; a stratified Wilcoxon-Mann-Whitney test. In all cases treatment effects, 95% confidence intervals and p-values will be reported. All analyses will be performed according to intention-to-treat. P-values $\leq .05$ will be considered significant. All statistical analysis was performed using SAS 9.4.