Misoprostol Effect on Second Trimester Abortion Blood Loss

Statistical Analysis Plan

NCT06078501

August 23, 2023

To detect a 30% reduction in the proportion of participants with quantitative blood loss (QBL) greater than the median, with a two-sided alpha of 0.05 and 80% power, we calculated that 36 participants per group would be needed. To allow for attrition, we planned to recruit 40 participants per group, for a total of 80 participants.

Descriptive statistics will be used to summarize baseline characteristics. Continuous variables will be compared using t-tests or Wilcoxon rank-sum tests, depending on distribution. Categorical variables will be compared using chi-square or Fisher's exact tests. Multivariable logistic regression was used to estimate the association between treatment group and the primary outcome (QBL greater than the median), adjusting for potential confounders.