

**Article Title:** Tranexamic Acid for Prevention of Hemorrhage in Elective Repeat Cesarean  
Delivery – A Randomized Study

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## **Statistical Analysis Plan**

Sample Size (total sample size=100, power 0.80, two-sided)

We selected a pilot of 20 patients randomly from schedule cesarean deliveries at Parkland Hospital. For this sample we performed the blood loss calculation for each delivery. This resulted in a mean blood loss of 2224 mL and a standard deviation of 362 mL. The trial is designed to observe a 205 mL reduction in the TXA arm over the placebo arms as from 2224 mL (placebo arm) to 2019 mL (TXA arm) with 80% power. This requires fifty patients randomized to each arm (one hundred total patients) using a two-sided test of significance level 0.05 using a Student's t-test.

Randomization was performed using a computer-generated table provided to the investigational drug pharmacy before patient recruitment. Randomization was according to randomized permuted blocks of size 6, 8, and 10. Data analysis included Pearson  $\chi^2$  for categorical data and Student's t-test for continuous data. P-values <0.05 were considered significant. Analyses were conducted with SAS version 4.1 (SAS Institute, Cary, NC).