STUDY TITLE: *Quadratus Lumborum Block versus Intrathecal Morphine for Postoperative Pain Control after Cesarean Delivery*

Principal Investigator: Nicholas J. Schott, MD

Source of Support: UPMC Department of Anesthesiology and Perioperative Medicine

NCT: 03261193

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STATISTICAL ANALYSIS PLAN

The primary outcome is the mean numeric rating scale (CRS) pain scores with activity 24-hours after completion of the quadratus lumborum block. Previous work comparing dynamic pain outcomes among women undergoing cesarean delivery with and without quadratus lumborum block 1 reported median (IQR) pain scores at 24-hours of 2 (0-3) in the intervention group and 4 (2-5) in the control group. Mean and standard deviation were estimated from this data using mean=median and SD = IQR/1.35.2. For 2 groups, a total sample of 60 subjects (~26 in each group completed) is estimated to achieve 80% power to detect differences among the NRS means versus the alternative of equal means using an F-test with a 0.05 significance level. The size of variation in the means represented by the standard deviation is assumed to be 1.00, with a common standard deviation within a group of 2.22. To account for subject dropout and/or ineligibility, 60 subjects will be screened for randomization into 2 groups, with 30 subjects to be screened for each group.

References:

1. Blanco R., Ansari T., Girgis E. Quadratus lumborum block for postoperative pain after cesarean section: A randomized controlled trial. Eur J Anaesthesiol. 2015 Nov; 32(11): 812-8.
2. Hozo SP., Djulbegovic B., Hozo I. Estimating the mean and variance from the median, range, and the size of a sample. BMC Med Res Methodol. 2005 Apr 20; 5:13.