Randomized Double Blinded Study Comparing Timing of PEC Block for Post-Operative Pain in Bilateral Mastectomy Patients

NCT Number: 03653988

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Document Date: October 3, 2018

Statistical Plan

The primary objective is to evaluate whether administration of a PEC I/II block post-mastectomy reduces average pain scores during post anesthesia care unit (PACU) and inpatient stay when compared to administration pre-mastectomy. Accordingly, a sample size of 34 patients ensured 80% power to detect a mean difference in pain scores of at least 2 as being clinically significant. Calculations were based on 1:1 randomization, a common standard deviation of 2, and using a two-sided, two-sample t-test evaluated at a 5% significance level. The secondary outcomes were average pain scores on POD 2, 3, 7, 14, 60 and 180 days, postoperative narcotic requirements, PACU and inpatient length of stay, complications, and readmission rates.

Chi-squared or Fisher's exact tests (where appropriate) were used to compare categorical variables, and Wilcoxon rank sum tests were used to compare continuous variables between treatment groups. Linear mixed effects regression models were used to assess treatment group differences in terms of pain scores, number of pills taken post-operatively, and PCS scores. Random effects were included to account for the longitudinally correlated nature of repeat assessments within a patient over time. All tests were two-sided and assessed for significance at the 5% level using SAS v9.4 (SAS Institute, Cary, NC).