

Study Title: A Pilot Study Investigating the nCAP Signal Relief Patch in Subjects Undergoing Primary Hip or Knee Replacement Surgery – A Pilot Trial

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Power calculation is for an anticipated 60 subjects who underwent TKA. Data is to be analyzed using intend-to-treat analysis plan. Data collection in this study includes the following measurements:

- Total opioid consumption (OME mg),
- Pain at rest and during movement rated on a standard Numerical Rating Scale (NRS, 0 = no pain and 10 = the worst pain imaginable),
- Area under the curve (AUC) for pain scores collected on POD 1, 2, 3, 7, 14, and 30,
- Time to discharge from the recovery room,
- Time to discharge from the hospital, and
- Overall subject satisfaction at the time of hospital discharge

The number of subjects requesting a prescription refill during the first 30-days post-operative will be calculated using the Pennsylvania Data Management Program.

Student's t-test, non-parametric Kruskal-Wallis test, or Pearson's chi-square test were used to determine differences in the distribution of continuous outcomes, and the chi-square test or exact test was used for differences in proportions for categorical outcomes between the treatment and placebo arms. Data will be presented as mean \pm standard deviation (SD) with a standard alpha set at 0.05.