Prevention of Persistent Pain and Opioid Use in Mothers – POMS

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Statistical Analysis Plan

All analyses used an intention to treat approach. All tests used a 2-sided p=0.05 (type I error). Data are presented as median [interquartile range, IQR] or number (percentage). Survival analysis was conducted using the Kaplan-Meier method to estimate the time to opioid cessation in gabapentin and placebo group. A log rank test was used to compare the time to opioid cessation in the two groups. Similar survival analyses were completed for time to pain relief and self-reported recovery. The data from NIH PROMIS questionnaires (depression, anxiety, fatigue, and physical function) were compared between the two groups using repeated measures mixed-effects model with unstructured covariance. Pairwise deletion was used for missing data. Analyses were performed with STATA version 14.0 (StataCorp, College Station, TX).