Study Title: *Methylnaltrexone versus Naloxegol in the Treatment of Opioid-Induced Constipation in the Emergency Department*

NCT number: *NCT03523520*

Date*: 09/04/2024*

Statistical analysis plan

Population: Patients with opioid-induced constipation refractory to other bowel regimens.

Feasibility: (sample size, frequency of eligible patients, duration of study):

Sample size: Sample size calculations were performed prior to study initiating resulting in the need for a total of 60 participants (14 in each arm [rounding up to 20 per arm], adding 18 participants to account for dropouts)

Frequency predictions for feasibility: 5 patients per month

Participants randomized in a 1:1:1 pattern assigned by pharmacy staff. Study investigators blinded to randomization and study drug.

Statistical considerations:

Previous statistical plan included frequency analyses by Chi-Square and parametric ANOVA calculations with pairwise comparisons.

Due to local changing prescribing patterns of opioids, the potential participant population was reduced to levels of infeasibility for continuation of this study. Therefore, only descriptive statistics were performed. No conclusive tests were performed.