Low Dose Ketamine as an Adjunct to Opiates for Acute Pain in the Emergency Department

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Statistical Analysis Plan:

Data will be recorded regarding patients' chief complaint/painful condition, number of prior visits for painful conditions, prior opioid use, initial pain level (as reported using the NRS-1116), pain level throughout the study (collected at 30-minute intervals), satisfaction with their pain control (collected at 30-minute intervals, beginning at T30), requirement for repeat doses of opioid analgesic, total amount of opioid given, vital signs (blood pressure, heart rate, respiratory rate, and oxygen saturation determined by pulse oximetry), sedation level (measured by the Ramsay scale18), any side effects experienced, age, race, sex, and other (nonopioid) medications/doses.

The study is powered for analysis using two-sided independent sample t tests, requiring a randomized sample size of 110 to provide 80% power to detect, independently a difference of 1.5 on the NRS-11 scale and/or a difference of 0.5 on the 4-point Likert scale.

The comparison of treatment groups across patient demographics and opioid usage will be implemented using Wilcoxon rank sum tests, chi-squared tests, and Fisher's exact test when cell sizes are small. Pain and satisfaction scores will be compared across treatment groups using linear mixed models as a function of treatment, time, and their interaction and with a random intercept. Upon visual inspection of the plotted pain level curves, a cubic time component will be implemented for pain level scores due to the expected curvature of the scores across time. All statistical analysis was performed in SAS (version 9, SAS Institute Inc.).