COVER SHEET

Sufentanil Infusion vs. Sufentanil Bolus and Time to Extubation during Routine Cardiac Surgery

NCT # 04226495

September 30, 2020

Sufentanil Infusion vs. Sufentanil Bolus and Time to Extubation during Routine Cardiac Surgery

Study Chairman or Principal Investigator:

Jeffrey Songster, MD

Assistant Professor, Department of Anesthesiology

University of Nebraska Medical Center

Supported by:

Department of Anesthesiology

University of Nebraska Medical Center

Study Intervention Provided by:

No support from pharmaceutical company or device manufacture.

NCT Number:

NCT # 04226495

PRÉCIS

Study Title

Sufentanil Infusion vs. Sufentanil Bolus and Time to Extubation during Routine Cardiac Surgery

Hypothesis

We hypothesize that routine cardiac surgery patients receiving sufentanil infusion will have a lower sufentanil concentration at the end of surgery and have a shorter time to extubation than patients receiving sufentanil bolus dosing even with similar total doses of sufentanil.

Objectives

Primary Outcome: Time the subject becomes extubated from stop data collection time point within the EMR.

Secondary Outcome: Plasma Sufentanil concentrations, Sufentanil pharmacokinetics, 24 hour post-operative pain scores, 24 hour opioid requirements in morphine equivalents, vasopressors and inotropes usage, ICU length of stay, Hospital length of stay, early re-intubation rate.

Design and Outcomes

Randomized single blind controlled clinical trial to test the benefit of sufentanil infusion over bolus dosing to reduce time to extubation and reduced length of ICU stay.

Interventions and Duration:
Intervention period: intra-operative sufentanil infusion vs intermittent bolus dosing the intervention will stop at the stop data collection time point within the operating room.

Post Intervention: Multiple lab draws at various time points to assess sufentanil concentrations and pharmacokinetics, we will follow pain scores and opioid requirements for 24 hours post intervention, we will follow the patient until discharge from the hospital for ICU length of stay and hospital length of stay. No further follow up after discharge. We anticipate a 24-48 hour ICU length of stay and a 5-7 day hospital length of stay.

Sample Size and Population

Adults between ages 19 and 80 with reasonable cardiac and pulmonary function presenting for routine cardiac surgery including coronary artery bypass graft and aortic valve replacement who qualify for “fast track extubation”. Based on estimates for time to extubation for our study population on sufentanil bolus dosing where we have an average time to extubation of 190.5 minutes (SD = 99 min) and assuming 80% power and statistical significance alpha level of 0.05, our power analysis suggests that we would

need to recruit at least 43 subjects into each intervention group for a total of 86 subjects giving the ability to detect a 60 min difference in time to extubation between groups. We plan on inflating this number to at least 100 subjects with approximately 50 subjects in each arm to allow for potential minimal losses in evaluable patients associated with unforeseen attrition related to exclusion criteria and censoring due to death or severely