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Title: Analyzing Data from the RACER Clinical Trial

Summary:

The Data Studio Workshop brings together a biomedical investigator with a group of experts for an in-depth session to solicit advice about statistical and study design issues that arise while planning or conducting a research project. This week, the investigator(s) will discuss the following project with the group.

Adequate perioperative analgesia is essential for best patient recovery and outcomes. Current analgesic techniques for cardiac surgery rely primarily on opioids, which are associated with significant adverse effects in multiple organ systems, potentially increasing patient morbidity and complications.

The erector spinae plane (ESP) block is a relatively new anesthesia technique performed by injecting local anesthetic into the interfascial plane between the erector spinae muscle and the transverse process. Bilateral thoracic ESP blocks and catheters, combined with a general anesthetic, have been described as effective regional anesthesia for cardiac surgery, may provide opioid-sparing effects, and may improve pain and recovery after surgery.

The RACER (Regional Anesthesia for Cardiothoracic Enhanced Recovery) study was designed as a double-blind, randomized, placebo-controlled trial in cardiac surgery patients undergoing sternotomy to determine if bilateral ESP catheters improve postoperative recovery parameters. At this stage we have complete data for 28 patients randomized to treatment arm and 32 patients randomized to placebo arm (pre-study power analysis needed 18 per group).

Our primary aim was to determine if local anesthetic via ESP catheters (treatment) reduces opioid requirements compared to patients receiving normal saline via ESP catheters (control). Secondary aims were to determine if local anesthetic via ESP catheters reduces pain scores, duration of mechanical ventilation, time to return of bowel function, and length of stay (LOS), or favorably shifts levels of pro- and anti-inflammatory biomarkers.

Questions:

Our questions concern the statistical analysis of data from the trial.

1. Pain Scores: We want to compare AUC for these scores during the first 5 post-operative days.
   (a) What is the best way to analyze AUC between groups?
(b) What is the most appropriate approach for null values should we consider them an empty cell or carry over value from previous data point?
(c) Is there an ideal way to break up time points? Currently datapoints are rounded to the nearest hour and graphed from 0 to 120 hours.

2. Uncommon Categorial Events: What is the best practice for analyzing such events?
   (a) Example 1: In the control group, 3 out of 32 experienced intolerable pain and study protocol was discontinued (0/28 in treatment group).
   (b) Example 2: In the treatment group, 2 out of 28 required no postoperative opioids (0/32 in control group).

3. Cytokines
   (a) What is the best method of comparing the ratio of cytokines (e.g., IL6:IL10) between groups?
   (b) What is the most appropriate statistical comparison when combining multiple cytokines into a ratio then comparing them to a clinical outcome (e.g., IL6/IL10 ratio compared to postoperative pain or opioid requirements)?
   (c) What is the best method to separate groups into high and low cytokine expression profiles?
   (d) If separated into quartiles what statistical test should we use?

Zoom Meeting Information
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