Data Studio

1:30–3:00pm, Wednesday, October 23, 2019
Conference Room X393, Medical School Office Building, 1265 Welch Road, Stanford, CA

Investigator: **Jessica Ansari** Clinical Assistant Professor, Department of Anesthesiology, Perioperative and Pain Medicine

Title: **Calcium Chloride in the Prevention of Uterine Atony during Cesarean**

Summary:

Maternal hemorrhage is globally the leading cause of maternal mortality. Furthermore, 80% of postpartum hemorrhage is caused by uterine atony which is a failure of the uterus to contract after separation of the placenta. Current drugs used to address uterine atony refractory to standard management with oxytocin are limited by cost, adverse side effect profiles, and common contraindications such as hypertension and asthma.

Calcium chloride is a widely-available, shelf-stable, cheap, and well-tolerated drug. Calcium is a key element in uterine muscle contractility. The mechanism of action for all drugs currently used for uterine atony depends upon myometrial calcium. Multiple studies utilizing uterine muscle strips from pregnant animals and humans have shown that increased extracellular calcium can improve strength and frequency of uterine contractions. Finally, many experienced obstetric anesthesiologists anecdotally use calcium to address cases of refractory uterine atony. However, there are no clinical studies that have examined the role of calcium chloride in this setting.

This pilot study is aimed to elucidate the potential role of calcium chloride plus standard of care for prevention of uterine atony in women at high risk undergoing Cesarean section. The design of this interventional pilot clinical trial is safety and efficacy with double-blind masking and parallel assignment via randomized allocation to either treatment or placebo for the purpose of prevention of uterine atony. A total of 40 parturients undergoing Cesarean with 2 or more accepted risk factors for uterine atony were block-randomized in a one-to-one ratio to receive an intravenous infusion of either calcium chloride or placebo at the time of fetal delivery. The primary aim is to determine if a single dose of calcium chloride compared to placebo administered immediately after fetal delivery can reduce the incidence of uterine atony in women at risk. The secondary aims are to determine whether intravenous calcium chloride reduces blood loss, improves maternal hemodynamics, and is well-tolerated with a favorable side-effect profile. The primary outcome is dichotomous: presence or absence of clinical uterine atony. The secondary outcomes include quantitative blood loss, subjective assessment of uterine tone from 0% (no tone) to 100% (excellent tone) by the obstetrician immediately after completion of study drug infusion, and change in hematocrit defined as preoperative baseline minus postpartum day 1.

Questions:

We need help to address the following questions.

1. How to choose feasible designs for subsequent clinical trials?
2. How to sequence trials that proceed from prevention to treatment?
3. How to identify the appropriate study population for each subsequent trial?

For more information about Data Studio:

http://med.stanford.edu/dbds/cool-tools/data-studio.html