Postpartum management of gestational hypertensive disorders using furosemide: A randomized controlled trial

Statistical Analysis Plan

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The statistical analysis plan is based on the objectives of the study as follows:

Main Question: Does the use of furosemide plus labetalol improve blood pressures in the postpartum period of patients with gestational hypertensive disorders versus labetalol alone?

Primary:

Does the addition of a 5-day course of furosemide to labetalol avoid the escalation of anti-hypertensive therapy to control blood pressures.

Analysis plan: Randomization groups (labetalol + furosemide vs labetalol alone) will be compared using a Fisher's Exact test for number of patients who have had an escalation of labetalol dose at any time during their hospital stay.

Secondary:

Does the addition of furosemide to labetalol in postpartum hypertension:

1. Improve of systolic blood pressure, diastolic blood pressure and mean arterial pressure.

   Analysis plan: Randomization groups will be compared on daily means for each outcome by repeated measures ANOVA to determine difference in outcomes across time (Day 0/Baseline, Day 1, and Day 2). One repeated measures ANOVA will be performed for each of the three outcomes (systolic blood pressure, diastolic blood pressure, and mean arterial pressure).

2. Shortened hospital stay

   Analysis plan: Randomization groups will be compared on hospital length of stay using a Student T-test.

3. Affect breastfeeding status at 1 week postpartum visit in mothers planning to breastfeed.

   Analysis plan: Randomization groups will be compared on breastfeeding status at the postpartum visit using a Fisher's Exact test.

4. Decrease readmission for postpartum hypertensive disorders.

Analysis plan: Randomization groups will be compared on the number of participants who were hospitalized after discharge using a Fisher's Exact test.