Study Title: Randomized Controlled Trial Comparing Nifedipine and Enalapril in Medical Resources Used in the Postpartum Period

NCT04236258

1/3/2022

Biostatistical analysis:

The primary outcome is a composite of additional medical resources used in the postpartum period in order to control hypertension and/or the symptoms associated with the antihypertensives. The composite includes prolonged hospitalization beyond the typical stay (>2 days for a vaginal delivery, >4 days for a cesarean delivery), unscheduled clinic visits, Labor and Delivery triage visits or a postpartum readmission. The primary outcome is binary; if a patient has at least one of the composite outcomes she is considered to have the primary outcome. The secondary outcomes will include time to sustained blood pressure control (hours from initiation of medication to no additional changes to regimen), need to add additional antihypertensives (yes/no), clinically significant episodes of hyper- or hypotension (yes/no), creatinine levels at one week after discharge and six weeks postpartum, continued need for antihypertensives one week after discharge and six weeks postpartum (yes/no), side effects (listed), adverse events (listed), patient reported compliance (yes/no) and a patient satisfaction survey administered on the day of discharge from the delivery admission. The appointments at one week after discharge and six weeks postpartum are standard practice.

We plan to analyze this trial on an intention-to-treat basis. The primary outcome will be measured as the proportion of patients within each group that had at least one of the composite outcomes. To determine the baseline rate of our primary outcome, we looked at a small sample of randomly selected patients with postpartum hypertension who were discharged home on antihypertensives and observed the primary outcome occurs 70% of the time in this cohort. We believe that a clinically relevant decrease in this outcome would be to decrease this proportion below 50%. Therefore, we have chosen 40% as our target for what we would consider a successful intervention. For sample size, we are assuming an alpha of 0.05 and a power of 80%. Using a two-sided T-test in R comparing proportions of the two outcomes, we determined we will need 40 participants in each arm. Accounting for possible lack of follow-up, we will aim to enroll 45 in each arm, for a total of 90 patients.