

Pregnancy-Related Hypertension: Adherence to a New Type of Monitoring (PHANTOM)

Statistical Analysis Plan – per study protocol dated 03.09.2021

Study Size and Power

Our sample size calculation for this study is based upon a prior published study investigating postpartum blood pressure ascertainment in a similar population of women with hypertensive disorders of pregnancy by Hirshberg et al. In their cohort, a blood pressure was obtained in 43.7% of patients in the usual care group versus 92.2% in the text-based blood pressure monitoring group. We will assume a slightly more conservative estimate of 50% blood pressure ascertainment in the usual care group and 70% in the text-based group. With a two-sided alpha of 0.05% and 80% power, we would need to enroll 93 patients in each arm for a total population of 186.

Analytic Plan

- Intention to treat analysis
- No exclusions for protocol violations or post-randomization exclusions
- Calculation of RR and 95% CI for primary outcome
- Univariate analysis of independent variables