

Date: 11/02/21

Title: Mechanisms of Refractory Hypertension (Reserpine)

NCT Number: NCT03223272

Date of Last Protocol Approval: 06/09/21

PI: David A. Calhoun, MD
University of Alabama at Birmingham
Birmingham, AL 35294

Study Protocol

1. Study Title: Mechanisms of Refractory Hypertension (Reserpine)
2. Hypothesis: Reserpine, a potent sympatholytic agent will substantially reduce blood pressure (BP) in patients with refractory hypertension.
3. Inclusion Criteria: Patients (age 19-80 years) referred to UAB Hypertension Clinic with refractory hypertension defined as uncontrolled office BP adherent with 5 or more antihypertensive agents, including a long-acting thiazide diuretic and spironolactone.
4. Exclusion Criteria: chronic kidney disease (eGFR <30 ml/min/1.73 mm), pregnancy
4. Primary Endpoint: Change in 24-hr ambulatory systolic BP
5. Study design: Subjects will be withdrawn from centrally-acting alpha-1 agonists agents (i.e., clonidine, guanfacine) over a 1-2-week period, if appropriate. A baseline 24-hr ambulatory BP monitoring will be done with subjects taking all of their normally prescribed antihypertensive agents. Subjects will then be dispensed reserpine 0.1 mg in open-label fashion to be taken daily for 4-weeks. At the end of the 4-week treatment period the 24-hr ambulatory monitoring will be repeated.
6. Statistical Plan: The protocol will be done as a proof-of-concept. Values will be presented as mean+/-standard deviation. Change in 24-hr ambulatory systolic BP from baseline to end-of-treatment will be compared by paired T-test.
7. Publication Plan: Study results will be presented at national hypertension meetings and submitted to a peer-reviewed medical journal for consideration of publication.