

PROTOCOL

Official title: MR Antagonist – Eplerenone vs Amolidipine and STRIATIN

Document number: NCT03683069

Date: 12/14/2024

Flow Chart – Study Design (FIG 1)

Subjects in the RPDR cohort were recruited to the study using Patient Gateway to specifically invite their participation. After documenting that the subject had the correct striatin genotype, current antihypertensive medications were discontinued. To assess the salt sensitivity of their blood pressure (**SSBP**) six - seven days of a restricted salt diet (**Visit 1**) was provided with blood pressure (**BP**) measured seated, daily in the morning at home and in the office at the end of the diet study. Then, the diet was changed to a liberal salt intake (**Visit 2**), and the BP studies were repeated. At the conclusion of the SSBP study, the subjects were randomized to the eplerenone or amlodipine arms and resumed a normal diet. After 3 weeks of the normal salt diet, the diet was changed to a liberal salt intake. Subjects continued to measure home BPs and returned to the clinic on the 7th day to have office BPs measured (**Visit 3**). If the last two home BPs were < 140/90 mmHg, goal BP was achieved, and the subjects were maintained on the present dose. If goal BPs were not achieved, then the doses were increased. The whole process is repeated for a second month (**Visit 4**); if goal BP is not achieved, a third dose increase is instituted, and the process is repeated for a third month (**Visit 5**). A 24-hour ambulatory BP was obtained at the time of randomization and at **Visit 5** on all subjects when they were on a liberal salt diet.

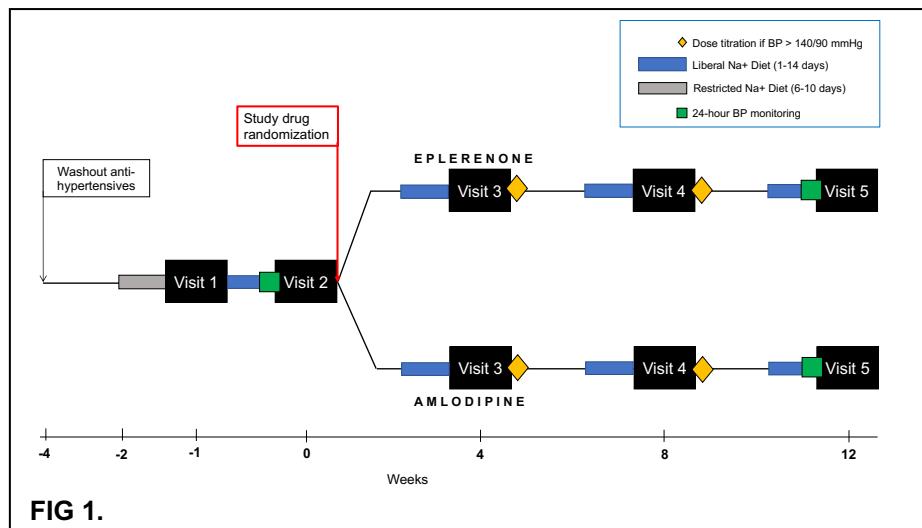


FIG 1.

Participant Flow – Consort Diagram (FIG 2)

There were 2786 individuals invited to participate in the study, of which 400 met the screening and genotype criteria. Of these, 67 were randomized to a treatment arm. Two subjects dropped out before receiving any medications. Thus, of the 65 enrolled, 33 were in the eplerenone limb and 32 in the amlodipine limb. All but one completed the entire study after randomization.

