WORK PLAN AND METHODS

Study Design

This is a prospective, open-label, randomized, parallel and comparative study.

1. The Amlodipine will be replaced by S-Amlodipine if BP was controlled by Amlodipine.

2. If BP was not controlled by Amlodipine and/or combination then S-Amlodipine will replace Amlodipine and dosage escalation will be done until target BP achieved.

3. If patient on combination with Amlodipine e.g. Amlodipine (5 mg) + Drug X (YY mg), we will replace with S-Amlodipine (2.5 mg) + Drug X (YY mg).
   a. Patients will be randomly divided into two groups.
   b. A total of 200 patients will be enrolled in the study. They will be randomized into two groups.
   c. Group A (100 patients) - Will receive Amlodipine 5 mg daily.
   d. Group B (100 patients) - Will receive S-Amlodipine 2.5 mg daily

Study Population: Outdoor patients who have been on treatment with Amlodipine 5 mg for mild to moderate hypertension will be enrolled in the study.

Primary Outcome Measures: To compare the efficacy of S-Amlodipine 2.5 mg with Amlodipine 5 mg upon switching the patients from Amlodipine to S-Amlodipine in the treatment of mild to moderate hypertension.

Secondary Outcome Measures: The intensity of treatment emergent adverse event (TEAE) and tolerability of S-Amlodipine.
Eligibility:

**Inclusion Criteria:**

- Age: Males and females aged 18 to 75 years (inclusive) at screening.
- Body mass index (BMI) between 18 and 35 kg/m² (inclusive) and body weight at least 40 kg at screening and prior to enrollment.
- Condition: Elevated BP >140/90 mmHg
- Male or female patients who are already on treatment with Amlodipine 5mg for stage 1 and stage 2 hypertension
- The patients who had not achieved target BP

**Exclusion criteria:**

- Hypersensitivity
- Mean SBP > 180 mmHg.
- Severe, malignant, or secondary hypertension.
- Episodes of hypertensive crisis or hypertensive emergency within 6 months prior to enrollment.
- Previous history of fainting, collapse, syncope, orthostatic hypotension, or vasovagal reactions considered to be of clinical significance.
- Severe coronary artery disease indicated by myocardial infarction, percutaneous coronary intervention, or coronary artery bypass graft within the last 12 months prior to enrollment.
- Angina pectoris within 6 months prior to enrollment