WORK PLAN AND METHODOLOGY

Study design: The study was designed as Prospective Observational Study.

Source of data:

Data relevant to study will collect directly from patient profile and laboratory investigational report of patients taking treatment either an Amlodipine 5 mg once in a day or Losartan 50 mg once in a day.

Study criteria:-

Eligibility:

Ages Eligible for Study: 18 Years and older

Genders Eligible for Study: Both

Inclusion Criteria:

✓ Female or male patient with age ≥ 18 years old.
✓ Patient with mild to moderate uncomplicated essential hypertension, and the blood pressure not adequately controlled on existing antihypertensive treatment.

Exclusion Criteria:

× Known or suspected secondary hypertension.

× sSBP > 200 mmHg or sDBP > 110 mmHg at baseline visit.

× Patients taking more than two anti-hypertensive medications at the screening visit.

× Known NYHA functional class Chronic Heart Failure (CHF) III and IV.

× With a history of myocardial infarction, transient ischemic attack or cerebrovascular accident within the preceding 6 months, clinically significant valvular heart disease, or hepatic and/or renal dysfunction as defined by the following laboratory parameters:

• SGPT (ALT) or SGOT (AST) > two times upper the limit of normal range
Serum creatinine > 2.3 mg/dl or creatinine clearance < 30 ml/min

**Study procedure:** In this study patients taking medicines will divide into two arms

Arm A: Patients who are taking losartan 50 mg OD.

Arm B: Patients who are taking amlodipine 5 mg OD.

**Collection of Data:** At baseline, patient details will collect and record in the patient data collection form. All the required data of the study patients including demographic details such as name, sex, age, address, occupation, clinical data such as diagnosis, blood pressure, other co-morbid diseases and other relevant details will collect from treatment chart and laboratory investigational reports.

Data was collected by using the following questionnaire:

1) Did he/she was having previous history of Hypertension?

2) If yes what treatment taken previously? What was the duration of that treatment?

3) Did he/she has past disease history other than Hypertension?

4) Any of their family members suffering with Hypertension? They have taken treatment or not?

5) Now what are the main complaints? How many days he/she suffering?

6) Did he/she taken any medication before coming to the hospital & what is that medication?

7) Any other diagnosis other than Hypertension from the present prescription?

8) Did he/she having smoking habit? If yes then duration of smoking?

9) Did he/she having drinking habit? If yes then duration of drinking?

**Efficacy:** Subjects will evaluate by measuring seating SBP and seating DBP at baseline & then at 3, 6, 9 & 12 week treatment period.
The primary outcome will be mean change in seating SBP at ITT (intent to treat) period of 12 week from mean baseline seating SBP. The secondary outcome will be mean change in seating DBP at ITT (intent to treat) period of 12 week from mean baseline seating DBP. In addition, the responder and controlled SBP rate & controlled DBP rate will be calculate. For measuring responder the criteria would be whom SBP at 12 week reach 120 mmHg & DBP at 12 week 80 mmHg. The controlled SBP rate is defined as: SBP <140 mmHg and SBP <130 mmHg. The controlled DBP rate is defined as: DBP <95 mmHg and DBP <90 mmHg.

**Evaluation parameters:**

- Blood Pressure Measurement

**Safety:**

For evaluating safety the questionnaire system will be use. The occurrences of adverse effects will be determine at each visit by asking the open-ended question: “Since we last met, has there been any change in the way you feel?”

**Statistical analysis:** The patient’s demographic characteristics at baseline will summarize and compare between the losartan group and the amlodipine group. Data for the categorical variables will be express as the number and percentage of patients, and the observed frequencies were compared using a Chi-square test. For continuous variables, data were expressed as (mean±SD) and the mean values will compared using an paired Student T test. For the safety analysis, AEs will evaluate and compare between the groups using the Fisher exact test. All data will analyze using the statistics software MINITAB 15.