A Randomized, Double-blind, Placebo Controlled, Parallel Study for the Assessment of Anti-hypertensive

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We are looking for volunteers to enroll in a clinical research study that will investigate the effect of a dietary supplement on changes in blood pressure in adults with mild or moderate hypertension. The study will last approximately 12 weeks. There will be 6 visits to our clinic during the study. Visit 3, Visit 5 and Visit 6 will be conducted over two days for the purposes of obtaining a 24 hour blood pressure measurement. Each visit will take approximately one hour or less to complete. The study product will be provided to you as, 2 tablets taken once a day for 56 days. You will be asked to maintain a study diary to record the time you take the study product each day. You will be required to wear an ambulatory blood pressure monitor for 24 hours 3 times during the study. You must be willing to have blood drawn 3 times during the study and for those visits you will come to the clinic fasting, nothing to eat or drink except water for 12 hours prior to those visits. You will also be asked to complete a 24 hour urine collection twice during the study. Prior to all study visits, you will be asked to abstain from alcohol for at least 48 hours, abstain from coffee for at least 14 hours and abstain from physical exercise for 4 hours You will be asked to complete a three day food record 3 times during the study.

Center /Company: KGK Synergize
IRB-HSR number: 2014-MAY-09
Primary Investigator (PI): Dr. Dale Wilson
Purpose of Study: We are looking for volunteers to enroll in a clinical research study that will investigate the effect of a dietary supplement on changes in blood pressure in adults with mild or moderate hypertension. The Purpose of this study is to assess the change in daytime ambulatory systolic blood pressure (SBP) and the change in office SBP during the 8 week intervention in the active group in reference to control.
Compensation Provided: Yes
Compensation Details: Compensation up to $250.00
Time Commitment: 12 Week Study with 6 Visits to the clinic
Procedures Required: Blood tests, Ambulatory Blood Pressure Monitor, 3-Day Food Records, 24-hour Urine Collection
Ages Eligibility: 30-75
Gender Eligibility: Male and Female
Healthy Volunteers: Both
Contact Person: Clinic Recruiter
Exclusion Criteria: 1. Women who are pregnant, breastfeeding, or planning to become pregnant during the course of the trial, 2. Body mass index ? 35 kg/m2, 3. Antihypertensive drug treatment, regular high dose NSAID treatment, use of cyclosporine or tacrolimus, 4. Any history of cardiovascular disease (myocardial infarction, unstable angina pectoris, coronary artery bypass graft, percutaneous transluminal coronary angioplasty, temporal ischemic attack) including stroke and congestive heart failure, 5. Dementia, hypertensive retinopathy, left ventricular dysfunction or peripheral artery disease, 6. Anemia, abnormal electrolytes, proteinuria, abnormal liver, kidney and thyroid function (except subjects on thyroid replacement therapy), Clinically significant biochemistry defined as:; • Serum Sodium: 148 mmol/L, •
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Fasting serum Glucose: >7.0 mmol/L, • Serum TSH: 4.5 mU/l, • Serum GGT: 2 upper limits of reference range, • eGFR: 1 year since last menstruation), OR, Female subject of childbearing potential must agree to use a medically approved method of birth control and have a negative urine pregnancy test result. Acceptable methods of birth control include: • Double-barrier method (condoms with spermicide or diaphragm with spermicide), • Hormonal contraceptives including oral contraceptives, hormone birth control patch (Ortho Evra), vaginal contraceptive ring (NuvaRing), injectable contraceptives (Depo-Provera, Lunelle), or hormone implant (Norplant System). • Intrauterine devices, • Vasectomy of partner, 3. Mild or moderate hypertension (SBP 140-160 mmHg and DBP >100 mmHg) (mean of office blood pressure measurements at the two first study visits during run-in period (visits 1 (-4 week) and 2 (-2 week)) and at baseline. Average office SBP baseline to be as close to 150 mm Hg (i.e. 147-149 mmHg) as possible., 4. Body weight 60kg, 5. Stable body weight (self-reported weight gain or loss