Clinical Trial: CARDIA-Salt Sensitivity of Blood Pressure (SSBP)

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Body

U.S., Feb. 13 -- ClinicalTrials.gov registry received information related to the study (NCT04258332) titled 'CARDIA-Salt Sensitivity of Blood Pressure (SSBP)' on Feb. 4.

Brief Summary: Salt sensitivity of blood pressure (SSBP) is defined as the change in blood pressure (BP) in relation to change in salt intake. An increase in BP from low- to high-salt diet is common and associated with an increased risk of cardiovascular morbidity and mortality, even among normotensive individuals. Yet, the pathophysiology of SSBP is not well understood. The prevailing paradigm is that abnormalities of neurohormones that regulate sodium (Na+) retention and excretion and/or Na+ transporting pathways create Na+ imbalances that underlie susceptibility to SSBP.

As a homeostatic mechanism, BP fluctuates to maintain Na+ balance, i.e. higher BP is needed for pressure natriuresis to excrete excess Na+. An alternate framework emphasizes vascular dysregulation as the inciting mechanism. In both constructs, how Na+ itself influences BP remains incompletely understood. Our preliminary work suggests that excess Na+ induces a pro-inflammatory state that sustains higher BP. Interleukin-6 (IL-6) drives the induction of interleukin-17 (IL-17) secreting T helper 17 cells that were recently demonstrated to be pathogenic in response to Na+ exposure. IL-6, IL-17 and related cytokines regulate renal Na+ transporters and raise BP through vascular inflammation, fibrosis, and impaired vasodilation. The immune response to high- and low-salt diet in humans, however, is not completely understood, emphasizing the need for more detailed human studies, with deeper immune profiling under controlled salt conditions and with neurohormonal assessment. Our overarching postulate is that the inflammatory response to excess dietary salt intake is associated with SSBP. The Coronary Artery Risk Development in Young Adults (CARDIA) study is the ideal cohort in which to translate our preliminary findings. Investigators propose to investigate SSBP in CARDIA using standardized low- and high-salt diets and 24-hour ambulatory BP monitoring. Investigators will quantify SSBP in a total of 500 participants from the Chicago and Birmingham field centers during the upcoming year 35 exam (beginning in 2020). Our specific aims are: 1) to define the distribution of SSBP and its clinical correlates in a contemporary community-based US cohort of middle-aged individuals; 2) to investigate the immune response to dietary salt loading, and 3) to investigate the association between the immune and BP responses to dietary salt loading. The proposed study represents a unique opportunity to leverage a large, well-phenotyped cohort to test novel hypotheses regarding SSBP. Phenotyping SSBP using standardized high- and low-salt diets in CARDIA will be novel as this has never been performed in any of the existing US based NHLBI sponsored cardiovascular epidemiologic cohorts. The proposed work has the potential to yield a more readily available approach for differentiating an individual as salt-sensitive or resistant. New insights into the pathophysiology of SSBP should also provide a foundation for investigating highimpact clinical applications, by informing future studies of therapies directed at SSBP. The scientific rigor is further enhanced by the rich clinical, genetic, and biochemical data available in CARDIA.

Study Type: Interventional

Condition: * Salt Sensitivity of Blood Pressure

Clinical Trial: CARDIA-Salt Sensitivity of Blood Pressure (SSBP)

* Hypertension

Intervention: * Dietary Supplement: High Salt Diet

Patients will be randomized to be on a high salt diet for 7 days.

* Dietary Supplement: Low Salt Diet

Patients will be randomized to be on a low salt for 7 days.

Recruitment Status: Not Yet Recruiting

Sponsor: Vanderbilt University Medical Center

Information provided by (Responsible Party): Deepak Gupta, Vanderbilt University Medical Center

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