PHREG - Pediatric Hypertension Registry
Protocol 01/03/19
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Background

Pediatric hypertension is increasingly common and is a precursor for adult cardiovascular and renal disease. But even during childhood, hypertension is associated with significant morbidity, including cognitive impairment and organ damage. However, the cause of pediatric hypertension, the response to treatment, and the mechanisms behind organ damage are incompletely understood. Due to these limitations, there are no first-line medications, and treatment is often inadequate. An improved comprehension of the course of pediatric hypertension could enhance clinical care. The goal of this proposal is to create a registry of patients with pediatric hypertension to better enable research into this important disease. This patient registry will enhance our ability to quickly collect and analyze data for research studies.

Study Design

*Inclusion and Exclusion Criteria*We will include all subjects evaluated at the Brenner Children's Hospital Pediatric Nephrology clinic since January 1st, 2013 with a diagnosis of hypertension 1) confirmed with three separate blood pressure measurements ≥90th %ile for age, sex, and height, or ≥120/80 or 2) by ambulatory blood pressure monitoring with blood pressure mean <95th %ile, blood pressure load <25%, or nocturnal dipping <10%. We will also include patients from Brenner's Enhanced Care Team database using the same criteria. We will exclude patients whose initial evaluation occurred on or after their 18th birthday. An additional site, Emory University Pediatric Nephrology will be using the same criteria to enroll subjects.

Retrospective Assessment

Brenner Children's Hospital Pediatric Nephrology will utilize i2b2 to identify our retrospective hypertension cohort. We will search for diagnosis codes of hypertension and related terms to retrospectively identify patients to be entered into the database. We anticipate a sample size of 500 subjects to be identified retrospectively at each site. Additional study sites may use i2b2 to identify subjects or a similar cohort at its discretion.

Prospective Assessment

Sites will recruit from patients prospectively seen in their Pediatric Nephrology clinics with a diagnosis of hypertension. We will obtain parental consent and subject assent for all enrolled subjects. There are no study-specific assessments or visits. No patient biologic samples will be collected. We anticipate enrolling 200 subjects per year.

Data Collection

Clinical data will be collected from the electronic medical record, including sex, parent-reported race, height, weight, body mass index, age at diagnosis, age at each visit, and past medical and family histories. We will define overweight/obesity as a body mass index ≥85th %ile for age and sex. We will record systolic and diastolic blood pressure and results of ambulatory blood pressure monitoring. We will note antihypertensive medication type and dosage. We will record standard clinical laboratory values, including sodium, potassium, chloride, CO_2, blood urea nitrogen, creatinine, uric acid, aspartate aminotransferase, alanine aminotransferase, lipid profile, vitamin D 25-OH, Hgb A1c, renin, aldosterone, thyroid stimulating hormone, free thyroxine, urine albumin, urine protein, urine creatinine, and presence of hematuria. We will calculate glomerular filtration rate to measure renal function standardized to age, sex, and height. We will record results of echocardiograms, renal ultrasounds, abdominal ultrasounds

with elastography, and vesicoureterograms. Every subject will be assigned a study ID, and all data will be de-identified and stored securely ina RedCap database that will be shared across study sites and that can store site-specific patient data separately.

References

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