

INTERVENTIONAL STUDY FOR CHILDREN WITH ADPKD

We are currently conducting a three-year randomized double-blind placebo controlled clinical trial of pravastatin treatment in children and young adults with ADPKD at The Children's Hospital in Aurora, Colorado. The principal investigators are Melissa Cadnapaphornchai, MD, and Robert W. Schrier, MD.

Eligibility criteria include otherwise healthy children and young adults with ADPKD who are between 8 and 21 years old and who have normal kidney function.

The study protocol includes three hospital visits over a three-year period. Each hospital visit will last two days and will involve blood pressure measurement, blood and urine studies, renal/cardiac MRI, and brachial artery ultrasonography. Study subjects will receive lisinopril and will be randomized to receive either pravastatin or placebo. Between hospital visits, participants will be asked to take the investigational medications and to record blood pressure measurements at home on a regular basis.

Potential benefits of participation include physical examination and laboratory and radiology studies. All expenses including study-related medications, a home blood pressure machine, travel costs to and from Denver (including one parent for children under 18 years of age), and laboratory and radiology testing, will be provided. There is no cost to the subject for participation in this research study. The subject will not be paid for participation in this research study.

This is research study #05-0704 as designated by the Colorado Multiple Institutional Review Board. Study participants will need to sign a specific consent form as well as a release for use of personal health information (HIPAA form). This study is registered with clinicaltrials.gov as NCT00456365.

Please contact Dr. Cadnapaphornchai with questions or concerns regarding this research study. Our toll-free number is 877-765-9297 and our email address is pkd.nurse@ucdenver.edu. Parents/subjects can also contact us directly.