

## Your Patient and HALT PKD

As the study moves forward, it may be necessary for HALT PKD to call on you from time to time to request your help with a participant who is under your care. A Study Investigator or Coordinator may contact you to:

- Request relevant medical records, including ultrasounds.
- Request certain lab tests (at study expense) for safety or follow-up.
- Request follow-up between study visits, if necessary.
- Request assistance in managing an adverse event.

HALT PKD will inform you of any medically significant abnormal results from laboratory tests and imaging studies if your patient authorizes release of his/her Protected Health Information (PHI).

If you have patients who could benefit from study participation, we invite them to learn more by contacting the HALT PKD Project Manager at (314) 362-1318.

They may also visit the HALT PKD website at [www.pkd.wustl.edu/pkdtm](http://www.pkd.wustl.edu/pkdtm).

- Travel reimbursement up to \$250, plus overnight stays, will be provided, if necessary.
- Clinic visits, lab tests, study medications and a home BP monitor will be provided at no charge.

## HALT PKD

### Participating Clinical Centers

Beth Israel Deaconess Medical Center, Boston, MA  
Principal Investigator: Dr. Theodore Steinman  
Call (Toll-Free): (866) 650-1815

Cleveland Clinic Foundation, Cleveland, OH  
Principal Investigator: Dr. William Braun  
Call (Toll-Free): (800) 223-2273, Extension 44680

Emory University, Atlanta, GA  
Principal Investigator: Dr. Arlene Chapman  
Call: (404) 686-8280

Kansas University Medical Center, Kansas City, KS  
Principal Investigator: Dr. Franz Winklhofer  
Call: (913) 588-7609

Mayo Clinic, Rochester, MN  
Principal Investigator: Dr. Vicente Torres  
Call (Toll-Free): (888) 630-2616

Tufts-New England Medical Center, Boston, MA  
Principal Investigator: Dr. Ronald Perrone  
Call (Toll-Free): (866) 846-2735

University of Colorado Health Sciences Center, Denver, CO  
Principal Investigator: Dr. Robert Schrier  
Call (Toll-Free): (877) 765-9297

Data Coordinating Center  
Washington University, St. Louis, MO  
Principal Investigator: Professor J. Philip Miller

Project Manager: Ms. Robin Woltman  
(314) 362-1318

[www.pkd.wustl.edu/pkdtm](http://www.pkd.wustl.edu/pkdtm)

### Information for Physicians

## HALT PKD

### A Clinical Research Study To HALT Progression of Polycystic Kidney Disease



Developed by the  
Polycystic Kidney Disease  
Treatment Network

Sponsored by  
The National Institute of Diabetes &  
Digestive & Kidney Diseases (NIDDK)  
The National Institutes of Health (NIH)  
U.S. Department of Health and  
Human Services

# HALT PKD—Information for Physicians

HALT PKD is a 4-6 year, multi-center study, funded by NIH, in which participants will be eligible for 1 of 2 studies, depending on their level of kidney function as measured by GFR.

## Study A

### Preserved Kidney Function (GFR > 60 mL/min/1.73 m<sup>2</sup>)

- **Purpose:** Evaluate efficacy of dual vs. single blockade of the renin-angiotensin system on kidney cyst growth using a combination of ACE inhibitor (ACE-I) and ARB vs. ACE-I alone and usual (120-130/70-80 mm Hg) vs. low blood pressure control (95-110/60-75 mm Hg). The ARB and control will be masked.
- **Outcome:** Percent change in kidney volume (cyst growth), as measured by MRI at baseline, 2 and 4 years.

## Study B

### More Advanced Kidney Disease (GFR 25- 60 mL/min/1.73 m<sup>2</sup>)

- **Purpose:** Evaluate efficacy of multi-level blockade of the renin-angiotensin system using a combination of ACE-I and ARB vs. ACE-I alone on slowing loss of kidney function independent of blood pressure control. The ARB and control will be masked.
- **Outcome:** Time to 50% reduction of baseline eGFR, ESRD, or death.

*HALT PKD may ask the primary care physician or nephrologist to obtain a serum creatinine sample (at study expense), on occasion, and forward it to the central laboratory at Cleveland Clinic for analysis.*

## Study Overview

Participants will take a combination of either Lisinopril (ACE-I) and Telmisartan (ARB) or Lisinopril and placebo, with doses titrated to maintain blood pressure (BP) within the assigned range. If necessary, a diuretic and additional antihypertensive medications will be added to maintain the BP goal. Participants will monitor BP at home, with a Study Coordinator phoning every 2 weeks during titration to discuss BP readings. Dose adjustments will be made according to protocol, based on these BP readings. Subsequent telephone contact will occur every 3 months. Follow-up visits at the study site will occur twice in the 1st year, then every 6 months until the study ends. Serum potassium and creatinine will be measured up to 4 times during the 8-week titration period and will be measured at each follow-up visit.

## Safety

HALT PKD requires additional safety testing (serum creatinine and potassium) for participants who meet either of the criteria below .

- Hyperkalemia—High normal or potassium level  $\geq 5.6$ .
- GFR <30 mL/min/1.73 m<sup>2</sup>

*HALT PKD will notify the primary care physician or nephrologist of any medically significant lab results if the participant has granted authorization for the study to release PHI.*

*HALT PKD may also ask the primary care physician or nephrologist to obtain the required safety labs, serum creatinine and potassium (at study expense), and forward the results to the study site.*

## Eligibility Criteria

### Inclusion Criteria

1. Diagnosis of ADPKD.
2. Age 15-49 (Study A); Age 18-64 (Study B).
3. GFR >60 mL/min/1.73 m<sup>2</sup> (Study A).  
GFR 25-60 mL/min/1.73 m<sup>2</sup> (Study B).
4. BP  $\geq 130/80$  or receiving treatment for hypertension.
5. Informed Consent.

### Exclusion Criteria

1. Pregnant/intention to become pregnant within 4-6 yrs.
2. Documented renal vascular disease.
3. Spot urine albumin-to-creatinine ratio of  $\geq 0.5$  (Study A) or  $\geq 1.0$  (Study B) and/or findings suggestive of kidney disease other than ADPKD.
4. Diabetes requiring insulin or oral hypoglycemic agents / fasting serum glucose of  $\geq 126$  mg/dl / random non-fasting glucose of  $\geq 200$  mg/dl.
5. Serum potassium >5.5 mEq/L for participants currently on ACE-I or ARB; >5.0 mEq/L for participants not currently on ACE-I or ARB.
6. History of angioneurotic edema or other absolute contraindication for ACE-I or ARB. Intolerable cough associated with ACE-I is defined as a cough developing within six months of initiation of ACE-I in the absence of other causes and resolving upon discontinuation of the ACE-I.
7. Indication (but not hypertension) for  $\beta$ -blocker or calcium channel blocker therapy, unless approved by site principal investigator.
8. Systemic illness necessitating NSAIDs, immunosuppressant or immunomodulatory medications.
9. Systemic illness with renal involvement.
10. Hospitalized for acute illness in past 2 months.
11. Life expectancy <2 years.
12. History of non-compliance.
13. Unclipped cerebral aneurysm  $\geq 7$ mm diameter.
14. Creatine supplements within 3 months of screening visit.
15. Congenital absence of a kidney (also total nephrectomy for Study B).
16. Known allergy to sorbitol or sodium polystyrene sulfonate.
17. Exclusions specific to MR imaging (Study A).