

A Study to See Iftolvaptan is Safe in Infants and Children Who at Enrollment Are 28 Days to Less Than 18 Years Old with Autosomal Recessive Polycystic Kidney Disease (ARPKD)

NCT04782258

Status	RECRUITING
Phase	Phase 3
Sponsor	Otsuka Pharmaceutical Development & Commercialization, Inc.
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (2)

- Male or female subjects between 28 days and less than 18 years of age, with clinical features that are consistent with a diagnosis of ARPKD.
- Ability for parent/legal guardian to provide written, informed consent prior to initiation of any trial-related procedures, and ability, in the opinion of the principal investigator, to comply with all the requirements of the trial. Ability to provide written informed assent from all subjects old enough per local laws to provide assent.

Exclusion (27)

- Premature birth (d 32 weeks gestational age) for infants 28 days to < 12 weeks of age.
- Anuria or RRT defined as intermittent or continuous hemodialysis, peritoneal dialysis, hemofiltration, hemodiafiltration or history of kidney transplantation.
- Evidence of syndromic conditions associated with renal cysts (other than ARPKD).
- Abnormal liver function tests including ALT and AST, > 1.2 × ULN (upper limit of normal).
- Has splenomegaly or portal hypertension (HTN).

... and 22 more (see full listing online)

Locations (23 total)

Children's National Medical Center, Washington D.C., District of Columbia, United States

Emory University Hospital, Atlanta, Georgia, United States

Northwestern University Feinberg School of Medicine - Ann & Robert H. Lurie Children's Hospital of Chicago - Neonatology, Chicago, Illinois, United States

... and 20 more locations