Safety, Tolerability and Pharmacokinetics of AZD1613 in Adults With Autosomal Dominant Polycystic Kidney Disease

NCT07228364

Status	RECRUITING
Phase	Phase 1
Sponsor	AstraZeneca
Enrollment	40 participants

Key Eligibility Criteria

Inclusion (4)

- Patients with ADPKD Mayo Class (IB-IE), as per clinical diagnosis (MIC) assessed centrally. Genetic testing results will not be used for eligibility purposes
- eGFR = 45 to 90 mL/min /1.73m2
- Body weight e 45 kg and body mass index within the range 18 to 35 kg/m2 (inclusive).
- Females are to be of non-childbearing potential

Exclusion (9)

- As judged by the investigator, any evidence of cardiac, vascular, and other renal conditions which in the investigator's opinion makes it undesirable for the participant to participate in the study.
- Positive hepatitis C antibody, hepatitis B virus surface antigen, or human immunodeficiency virus test, at screening.
- History of QT prolongation associated with other medications that required discontinuation of that medication.
- Congenital long QT syndrome.
- History of ventricular arrhythmia requiring treatment. Patients with atrial fibrillation/flutter and controlled ventricular rate HR \< 100 bpm can be eligible as judged by the investigator.

... and 4 more (see full listing online)

Locations (15 total)

Research Site, Birmingham, Alabama, United States
Research Site, Loma Linda, California, United States
Research Site, Jacksonville, Florida, United States
... and 12 more locations