

Study to Assess the Efficacy, Pharmacokinetics, Safety and Tolerability of Iptacopan in Pediatric Patients With Primary IgAN

NCT06994845

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	31 participants

Key Eligibility Criteria

Inclusion (9)

- Male and female participants 2 to < 18 years of age as of Day 1.
- eGFR ≥ 30 mL/min/1.73m² where eGFR is calculated using the modified Schwartz formula at Screening and confirmed during the Run-in Period.
- Kidney biopsy-proven primary IgAN^{*}, with biopsy performed within 3 years of Screening with < 50% tubulointerstitial fibrosis and < 25% crescents. In case a kidney biopsy within 3 years from Screening is not available, a kidney biopsy may be performed if it is part of the planned diagnostic approach and clinical management of the participant.
- ^{*}Note: Primary IgAN is defined as any IgAN that is proven by biopsy showing IgA deposits prevalent over the other classes of immunoglobulins and deemed not to be associated with causes of secondary IgAN as per clinical judgment of the Investigator.
- The minimum body weight for participants in Cohort 1 is 35 kg at Screening and confirmed at Baseline (Day 1).

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

Exclusion (14)

- Any secondary IgAN observed at Screening (and confirmed at Baseline/Day 1) as defined by the Investigator; secondary IgAN can be associated with cirrhosis, celiac disease, human immunodeficiency virus (HIV) infection, herpes simplex virus infection, dermatitis herpetiformis, seronegative arthritis, small-cell carcinoma, lymphoma, disseminated tuberculosis, bronchiolitis obliterans, inflammatory bowel disease, and familial mediterranean fever.
- A clinical diagnosis of immunoglobulin A vasculitis (IgAV or Henoch-Schonlein purpura) based on typical palpable purpura with or without arthralgia and abdominal pain.
- Evidence of significant urinary obstruction or difficulty in voiding at Screening (and confirmed at Baseline/Day 1); any urinary tract disorder or any chronic kidney disease other than IgAN at Screening and before first study drug administration.
- Current acute kidney injury (AKI) defined by Acute Kidney Injury Network (AKIN) criteria within 4 weeks of screening.
- Presence of rapidly progressive glomerulonephritis (RPGN) as defined by 50% decline in eGFR within 3 months prior to Screening or during the Screening and Run-in periods.

... and 9 more (see full listing online)

Locations (15 total)

Childrens Hospital Colorado, Aurora, Colorado, United States
Childrens Hospital of Philadelphia, Philadelphia, Pennsylvania, United States
Prim Childrens Hosp Inv Pharm, Salt Lake City, Utah, United States

... and 12 more locations

<https://clinicaltrials.gov/study/NCT06994845>

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