

# Study of Efficacy and Safety of Iptacopan in Patients With C3 Glomerulopathy.

NCT04817618

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<b>Status</b>	RECRUITING
<b>Phase</b>	Phase 3
<b>Sponsor</b>	Novartis Pharmaceuticals
<b>Enrollment</b>	98 participants

## Key Eligibility Criteria

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### Inclusion (8)

- Male and female participants age e 12 and d 60 years at screening.
- Diagnosis of C3G as confirmed by renal biopsy within 12 months prior to enrollment in adults and within 3 years in adolescents.
- Prior to randomization, all participants must have been on a maximally recommended or tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) for at least 90 days. The doses of other antiproteinuric medications including mycophenolic acid, corticosteroids and mineralocorticoid receptor antagonists should be stable for at least 90 days prior to randomization.
- Reduced serum C3 (defined as less than 0.85 x lower limit of the central laboratory normal range) at Screening.
- UPCR e 1.0 g/g sampled from the first morning void urine sample at Day -75 and Day -15.

... and 3 more (see full listing online)

### Exclusion (10)

- Participants who have received any cell or organ transplantation, including a kidney transplantation.
- Rapidly progressive crescentic glomerulonephritis defined as a 50% decline in the eGFR within 3 months with renal biopsy findings of glomerular crescent formation seen in at least 50% of glomeruli.
- Renal biopsy showing interstitial fibrosis/tubular atrophy (IF/TA) of more than 50%
- Monoclonal gammopathy of undetermined significance (MGUS) confirmed by the measurement of serum free light chains or other investigation as per local standard of care.
- Participants with an active systemic bacterial, viral or fungal infection within 14 days prior to study treatment administration

... and 5 more (see full listing online)

## Locations (87 total)

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Childrens Hospital Colorado, Aurora, Colorado, United States  
Nicklaus Childrens Hospital, Miami, Florida, United States  
Georgia Nephrology Research Inst, Lawrenceville, Georgia, United States  
... and 84 more locations