

# Study to Evaluate Avacopan in Combination With a Rituximab or Cyclophosphamide-containing Regimen, in Children From 6 Years to < 18 Years of Age With AAV.

NCT06321601

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Status	RECRUITING
Phase	Phase 3
Sponsor	Amgen
Enrollment	20 participants

## Key Eligibility Criteria

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### Inclusion (6)

- Male and female children and adolescents from 6 to < 18 years of age
- Clinical diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), consistent with Chapel-Hill Consensus Conference definitions (Jennette et al, 2013)
- Newly diagnosed or relapsed AAV with positive test for anti-PR3 or anti-MPO antibodies
- At least 1 PVAS major item, at least 3 PVAS nonmajor items, or at least the 2 renal items of proteinuria and hematuria.
- eGFR  $\geq$  15 mL/min/1.73 m<sup>2</sup> (using modified Schwartz equation per central lab guidelines)
- ... and 1 more (see full listing online)

### Exclusion (3)

- Any other known multisystem autoimmune disease including eosinophilic granulomatosis with polyangiitis (Churg-Strauss), systemic lupus erythematosus, IgA vasculitis (Henoch-Schönlein), rheumatoid vasculitis, Sjogren's syndrome, anti-glomerular basement membrane disease, or cryoglobulinemic vasculitis
- Alveolar hemorrhage requiring invasive pulmonary ventilation support anticipated to last beyond the screening period of the study
- Any medical condition requiring or expected to require continued use of immunosuppressive treatments, including corticosteroids that may cause confoundment with study assessments and study conclusions.

## Locations (30 total)

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Emory University, Atlanta, Georgia, United States  
Riley Hospital for Children, Indianapolis, Indiana, United States  
University of Minnesota Masonic Childrens Hospital Discovery Clinic, Minneapolis, Minnesota, United States  
... and 27 more locations

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<https://clinicaltrials.gov/study/NCT06321601>

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