

A Phase 3, Open label, Uncontrolled Single-arm Study to Evaluate the Efficacy, Pharmacokinetics, and Safety of Avacopan in Combination With a Rituximab or Cyclophosphamide-containing Regimen in Children from 6 Years to less than 18 Years of Age with Active ANCA-associated Vasculitis (AAV)

Status: Recruiting

Eligibility Criteria

Sex: Male or Female

Age Group: Up to 18 years old

This study is NOT accepting healthy volunteers

Inclusion Criteria:

- 6 to 17 years old - diagnosis of granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA) - newly diagnosed or relapsed AAV with positive test for anti-PR3 or anti-MPO antibodies - weigh at least 15 kg (33 lbs)

Exclusion Criteria:

- any other known multisystem autoimmune disease - any medical condition requiring or expected to require continued use of immunosuppressive treatments, including corticosteroids

Conditions & Interventions

Interventions:

Drug: Avacopan

Conditions:

Rare Diseases

Keywords:

AAV, Active ANCA-associated Vasculitis, Vasculitis

More Information

Description: Blood vessel inflammation can damage parts of the body. The medicines we use to treat AAV try to turn off the blood vessel inflammation to prevent damage to the body. The purpose of this study is to see how safe and how well a medicine called avacopan works when combined with a child's regular medicine used to treat their AAV. This medicine is not approved in children, so will be called a "study drug."

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