

A Study to Evaluate Avacopan in Participants With ANCA-associated Vasculitis

NCT06072482

Status	RECRUITING
Phase	Phase 4
Sponsor	Amgen
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (6)

- Participants has provided informed consent before initiation of any study-specific activities/procedures.
 - Newly diagnosed or relapse of granulomatosis with polyangiitis or microscopic polyangiitis, consistent with Chapel-Hill Consensus Conference definitions (Jennette et al, 2013), where induction treatment with cyclophosphamide or rituximab is needed.
 - Age \geq 18 years (or \geq legal age within the country if it is older than 18 years).
 - Positive test for anti-positive antiproteinase 3 or antimyeloperoxidase (current or historic) antibodies.
 - At least 1 Birmingham Vasculitis Activity Score (BVAS) major item, or at least 3 BVAS nonmajor items, or at least the 2 renal items of proteinuria and hematuria.
- ... and 1 more (see full listing online)

Exclusion (28)

- Alveolar hemorrhage requiring invasive pulmonary ventilation support anticipated to last beyond the screening period of the study.
 - Any other known multisystem autoimmune disease that may confound study assessments and study conclusions including but not limited to eosinophilic granulomatosis with polyangiitis (GPA [Churg-Strauss]), systemic lupus erythematosus, immunoglobulin (Ig) A vasculitis (Henoch-Schönlein), rheumatoid vasculitis, Sjogren's syndrome, anti-glomerular basement membrane disease, or cryoglobulinemic vasculitis.
 - Any other medical condition requiring or expected to require continued use of immunosuppressive therapies, including corticosteroids that may cause confoundment with study assessments and study conclusions.
 - Received dialysis or plasma exchange within 16 weeks before Day 1 randomization.
 - Have had a kidney transplant.
- ... and 23 more (see full listing online)

Locations (68 total)

Orthopedic Physicians Alaska, Anchorage, Alaska, United States
Scottsdale Healthcare at Shea - HonorHealth, Scottsdale, Arizona, United States
Southwest Kidney Institute, Surprise, Arizona, United States
... and 65 more locations

<https://clinicaltrials.gov/study/NCT06072482>

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