

Safe Effective Therapy With Low-Dose Glucocorticoid in ANCA-Associated Vasculitis (SAFE-LOW)

NCT06983821

Status	RECRUITING
Phase	Phase 3
Sponsor	Ottawa Hospital Research Institute
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (5)

- New diagnosis of, or relapse of, granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA), consistent with Chapel-Hill consensus definitions
- Positive ELISA test for anti-myeloperoxidase (MPO) or anti-proteinase 3 (PR3)
- Severe kidney involvement from active AAV, characterised by both of the following:
- eGFR < 40 ml/min/1.73m² (Patients known to have a stable eGFR < 40 ml/min/1.73m² for > 3 months prior to enrollment are NOT eligible)
- Biopsy proven at least focal necrotizing/crescentic glomerulonephritis OR active urinary sediment by microscopy (greater than or equal to 10 red blood cells [RBC]/high power field with erythrocyte casts or greater than or equal to 20% dysmorphic RBCs or greater than or equal to 5% acanthocytes without an alternative cause.

Exclusion (11)

- A diagnosis of vasculitis other than GPA or MPA (including eosinophilic granulomatosis with polyangiitis, IgA vasculitis, cryoglobulinemic vasculitis, rheumatoid vasculitis)
- Positive anti-glomerular basement membrane antibody test or renal biopsy demonstrating linear glomerular immunoglobulin deposition
- A diagnosis of systemic lupus erythematosus or Sjögren's syndrome
- Receipt of dialysis for > 21 days immediately prior to randomization or prior renal transplant
- Age < 18

... and 6 more (see full listing online)

Locations (2 total)

St-Joseph's Hospital, Hamilton, Ontario, Canada
The Ottawa Hospital, Ottawa, Ontario, Canada

<https://clinicaltrials.gov/study/NCT06983821>

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