

PS-002 for the Treatment of IgA Nephropathy in Adults

NCT07182227

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Purespring Therapeutics Limited
Enrollment	32 participants

Key Eligibility Criteria

Inclusion (6)

- Diagnosis of primary IgA nephropathy (IgAN) as evidenced by renal biopsy.
 - A historic kidney biopsy performed within 36 months prior to screening with reported evidence of complement component 3 (C3) deposition. If the participant had a kidney biopsy performed over 36 months prior to Screening, a new kidney biopsy should be carried out during the Screening period. This biopsy must exhibit signs of ongoing complement system activity.
 - Proteinuria as assessed at the Screening visit by UPCR at least 1g/g (at least 1000 mg/g) OR total protein excretion at least 1 g/24 h (at least 1000 mg/24h) sampled from 24 h urine collection.
 - eGFR calculated using the CKD-EPI formula at least 45 mL/min/1.73m².
 - Sitting office systolic blood pressure equal to or less than 140 mmHg, diastolic blood pressure equal to or less than 90 mmHg.
- ... and 1 more (see full listing online)

Exclusion (15)

- A participant has nephrotic syndrome, defined for this purpose as 24 h urine protein greater than 3.5g with concurrent hypoalbuminemia (serum albumin less than 3.0 g/dL [less than 30 g/L]).
 - Any secondary IgAN defined as associated with gastrointestinal and liver disorders (liver cirrhosis, celiac disease, Crohn's disease, ulcerative colitis), autoimmune disorders (dermatitis herpetiformis, psoriasis, seronegative arthritis, systemic lupus erythematosus, rheumatoid arthritis), malignancy (IgA myeloma, lymphoma, lung cancer, renal cell cancer, cutaneous T-cell lymphoma), respiratory disorders (bronchiolitis obliterans, idiopathic pulmonary fibrosis) etc.
 - Having a major concurrent non-IgAN-related disease that, in the opinion of the investigator, prevents the assessment of IgAN.
 - History of malignancy; or bone marrow or organ transplant.
 - History of, or currently active primary or secondary immunodeficiency, including known history of human immunodeficiency virus infection, and other severe immunodeficiency blood disorders.
- ... and 10 more (see full listing online)

Locations (11 total)

University of Miami Hospital, Miami, Florida, United States
The Johns Hopkins Hospital, Baltimore, Maryland, United States
University of Michigan Hospital, Ann Arbor, Michigan, United States
... and 8 more locations

<https://clinicaltrials.gov/study/NCT07182227>

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