

Study of Efficacy and Safety of Iptacopan in Participants With IC-MPGN

NCT05755386

Status	RECRUITING
Phase	Phase 3
Sponsor	Novartis Pharmaceuticals
Enrollment	106 participants

Key Eligibility Criteria

Inclusion (7)

- Male and female patients including adults (aged at least 18 years to d 60 years) and adolescents (12 -17 years in non-EU countries at screening and 16-17 years in EU countries at screening).
- Diagnosis of idiopathic IC-MPGN as confirmed by kidney biopsy within 12 months prior to screening in adults and within 3 years of screening in adolescents (a biopsy report, review and confirmation by the Investigator is required). If such a biopsy is not available in an adult participant, this must be obtained at screening (performed and assessed locally for adults only).
- Prior to randomization, all participants must have been on a maximally recommended or tolerated dose of renin angiotensin system inhibitors (RASi), e.g an ACEi or ARB for at least 90 days (or as according to local guidelines). The doses of other drugs administered to reduce proteinuria and control the disease including mycophenolic acids (MPAs - mycophenolate mofetil or mycophenolate sodium), corticosteroids, SGLT2 inhibitors and mineralocorticoid receptor antagonists should be stable for at least 90 days prior to randomization
- UPCR e 1.0 g/g (e 113 mg/mmol) sampled from the first morning void urine sample at Day -75 and Day -15
- Estimated GFR (using the chronic kidney disease [CKD]-EPI formula for adult participants and modified Schwartz formula for adolescents aged 12 to 17 years) or measured GFR e 30 ml/min/1.73m² at screening and Day -15.

... and 2 more (see full listing online)

Exclusion (21)

- Participants who have undergone cell or solid organ transplantation, including kidney transplantation.
- Participants diagnosed with secondary IC-MPGN including but not limited to any of the following conditions:
- Deposition of antigen-antibody immune complexes as a result of any chronic infections, including
- Hepatitis C virus (HCV) including HCV-associated mixed cryoglobulinemia, hepatitis B virus (HBV);
- Bacterial-endocarditis, infected ventriculo-atrial shunt, visceral abscesses, leprosy, meningococcal meningitis; chronic bacterial infections

... and 16 more (see full listing online)

Locations (124 total)

Ronald Reagan UCLA Medical Center, Los Angeles, California, United States
Univ Cali Irvine ALS Neuromuscular, Orange, California, United States
UCSF, San Francisco, California, United States
... and 121 more locations

<https://clinicaltrials.gov/study/NCT05755386>

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