Study to Evaluate the Impact of Iptacopan on Top of SOC on Biopsy Changes in Kidneys of Adult Patients With IgAN

NCT06797518

Status	RECRUITING
Phase	Phase 2
Sponsor	Novartis Pharmaceuticals
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (7)

- Signed informed consent must be obtained prior to participation in the study; participants should be able to communicate well with the investigator, understand and comply with the requirements of the study.
- Male and female participants e18 years of age with biopsy-confirmed IgA nephropathy and an eGFR e 30 mL/min/1.73m2. eGFR will be calculated using the CKD-EPI 2009 formula.
- Proteinuria as assessed at screening by UPCR e 0.8g/g or 1g/d sampled from FMV.
- Biopsy at baseline should confirm IgAN with \< 50% tubulointerstitial fibrosis.
- Participants must be on ACEi or ARB treatment at either the locally approved maximal daily dose or the maximally tolerated dose (per investigators' judgment) for approximately 90 days prior to baseline visit and continue on a stable dose throughout the study. Participants with allergies or intolerance to ACEi and ARB are eligible for the study, but the investigator should clearly document the reasons for not being on maximal ACEi/ARB dose in the source documents. In addition, if participants are taking diuretics, other antihypertensive medication or Sodium-Glucose Co-Transporter 2 inhibitors (SGLT2i), the doses should be stabilized for at least 90 days prior to baseline.

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

Exclusion (34)

- Any secondary IgAN (at historic or baseline biopsies) as defined by the investigator and IgA vasculitis Henoch-Scholein Purpura (HSP). Secondary IgAN can be associated with cirrhosis, celiac disease, Human Immunodeficiency Virus (HIV) infection, dermatitis herpetiformis, seronegative arthritis, small-cell carcinoma, lymphoma, disseminated tuberculosis, bronchiolitis obliterans, and inflammatory bowel disease, familial Mediterranean fever, etc.
- Any secondary diagnosis at baseline biopsy (other than IgA nephropathy).
- Evidence of significant urinary obstruction or difficulty in voiding; any urinary tract disorder other than IgAN at screening and before first study drug administration.
- Current or planned usage of any homeopathic and/or herbal medications for IgAN disease progression, such as but not limited to Lei Gong Teng.
- Current acute kidney injury (AKI) defined by Acute Kidney Injury Network (AKIN) criteria within 4 weeks of screening.

... and 29 more (see full listing online)

Locations (16 total)

University of Alabama at Birmingham, Birmingham, Alabama, United States
UCLA Medical Center, Los Angeles, California, United States
Central Florida Kidney Specialists, Orlando, Florida, United States
... and 13 more locations