A multicenter, single arm, open-label trial to evaluate efficacy and safety of oral, twice daily iptacopan in adult PNH patients who have Hb >=10 g/dL in response to anti-C5 antibody and switch to iptacopan

Status: Recruiting

Eligibility Criteria

Sex: Male or Female
Age Group: 18 years and over
This study is NOT accepting healthy volunteers

Inclusion Criteria:

- diagnosis of Paroxysmal Nocturnal Hemoglobinuria PNH) - hemoglobin level at least 10 g/dL

•on a stable regimen (dose and intervals) of anti-C5 antibody treatment (either eculizumab or ravulizumab) for at least 6 months

Exclusion Criteria:

- needed red blood cell transfusion in the past 6 months - history of stem cell transplant or solid organ transplant - Human immunodeficiency virus (HIV) infection (known history of HIV or test positive for HIV antibody) - history of cancer of any part of the body within the past 5 years

Conditions & Interventions

Conditions:
Rare Diseases
Keywords:
Clinics and Surgery Center (CSC), Paroxysmal Nocturnal Hemoglobinuria, PNH

More Information

Description: The purpose of the study is to find out if iptacopan is effective and safe in adult patients with Paroxysmal Nocturnal Hemoglobinuria (PNH) who switch from their current standard of care treatment (eculizumab or ravulizumab) to iptacopan.
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IRB Number: STUDY00018020

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