A Phase 3 open-label, controlled, randomised, multi-centre trial comparing imlifidase and standard-of-care with standard-of-care alone in the treatment of severe anti-GBM antibody disease (Goodpasture disease)

Status: Recruiting

Eligibility Criteria

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

Inclusion Criteria:

- Anti-GBM antibodies constituting an indication for Plasma exchange (PLEX) - presence of blood or sediment in urine

Exclusion Criteria:

- diagnosis of anti-GBM disease made more than 14 days ago - women who are pregnant or breast feeding - additional exclusion criteria (study staff will review)

Conditions & Interventions

Interventions:
Drug: Cyclophosphamide (CYC), Drug: Glucocorticoids, Drug: Imlifidase, Procedure: Plasma exchange (PLEX)
Conditions:
Rare Diseases, Kidney, Prostate & Urinary
Keywords:
Anti-Glomerular Basement Membrane Disease, Good Pasture Syndrome, Goodpasture Syndrome

More Information

Description: The purpose of the trial is to evaluate the effect and safety of imlifidase when given to participants with antiGBM disease (also called Goodpasture disease). We will study if the addition of imlifidase to the standard of care treatment results in a better effect without causing unacceptable side effects compared to standard of care alone.
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