Post Approval Study of Liposorber LA-15 System for the Treatment of Focal Segmental Glomerulosclerosis in Children

Status: RECRUITING

Eligibility Criteria

Age: Up to 21 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

* A pediatric patient is deemed suitable for inclusion in the study if the patient has FSGS with a GFR ≥ 45 ml/min/1.73 m 2 and any of the following: * Refractory nephrotic syndrome in which standard treatment options are unsuccessful (i.e., patient is unresponsive to standard corticosteroid and/or calcineurin inhibitor therapy for at least 8 weeks resulting in failure to achieve complete or partial remission); * Refractory nephrotic syndrome in which standard treatment options are not well tolerated (i.e., patients intolerant to standard therapies due to severe side effects that negatively affect quality of life without providing an acceptable level of clinical benefit); * Refractory or recurrent nephrotic syndrome in which standard therapy is contraindicated. or - Pediatric post renal transplant patients with nephrotic syndrome associated with primary FSGS.

Exclusion Criteria:

* General Exclusion Criteria * Patient is greater than 21 years of age * Parent or patient is unwilling or unable to sign and date the informed consent (Note: Only patients 18-21 years of age may sign the informed consent on their own behalf) * Pregnant, lactating, or planning to become pregnant prior to completing the study (Note: The safety of the use of Liposorber® in pregnant women has not been studied. There may be unknown risks to an embryo/fetus. Sexually active women of child bearing potential should avoid pregnancy during the use of the Liposorber device and throughout the study duration.) * Unable or unwilling to comply with the follow-up schedule * Simultaneously participating in another investigational drug or device study * Body weight \< 15 kg (33.1 lbs) * Medical Exclusion Criteria * Currently being administered ACE inhibitors that cannot be withheld for at least 24 hours prior to each apheresis treatment (Note: The time period to withhold ACE inhibitors should be prolonged, if determined by the treating physician, considering each individual's renal function and the biological half-life of the ACE-inhibitor currently in use.) * Currently being administered antihypertensive drugs other than ACE inhibitors (e.g., Angiotensin II receptor blockers (ARBs) that cannot be withheld on the day of apheresis until after the procedure * Medical condition or disorder that would limit life expectancy to less than the primary clinical study endpoint or that may cause noncompliance with the study plan or confound the data analysis * Hypersensitivity to dextran sulfate, heparin, or ethylene oxide * Adequate anticoagulation cannot be achieved due to severe hemophilia, severe hemorrhage diathesis, severe gastrointestinal ulcers, or are recipients of vitamin K antagonist medications * Extracorporeal circulation therapy with Liposorber® LA-15 System cannot be tolerated due to severe cardiac insufficiency, acute myocardial infarction, severe cardiac arrhythmia, acute apoplexy, severe uncontrollable hypertension, or severe uncontrollable hypotension * Cardiac impairments such as uncontrolled arrhyth¬mia, unstable angina, decompensated congestive heart failure, or valvular disease * Functional thyroid disease or liver abnormalities * Unresolved systemic or local infection that could affect the clinical study outcomes

Conditions & Interventions

Interventions:
DEVICE: LIPOSORBER® LA-15 System
Conditions:
Focal Segmental Glomerulosclerosis
Keywords:
pediatric, renal transplantation, recurrence, drug-resistant

More Information

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