Post Approval Study for Treatment of Drug-resistant Adult and Pediatric Primary FSGS Using the LIPOSORBER® LA-15 System

NCT04065438

Status	RECRUITING
Phase	Not Applicable
Sponsor	Kaneka Medical America LLC
Enrollment	35 participants

Key Eligibility Criteria

Inclusion (4)

- A patient is deemed suitable for inclusion in the study if the patient has nephrotic syndrome associated with primary FSGS when:
- • Standard treatment options, including corticosteroid and/or calcineurin inhibitors, are unsuccessful or not well tolerated and the patient's glomerular filtration rate (GFR) e 45 ml/min/1.73 m2.
- or
- • The patient is post renal transplantation.

Exclusion (15)

- Patient is greater than 75 years of age at the start of the treatment period or less than 22
- The patient is unwilling or unable to sign and date the informed consent
- 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 childbearing 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

... and 10 more (see full listing online)

Locations (10 total)

Loma Linda University Children's Hospital, Loma Linda, California, United States
Loma Linda University Hospital, Loma Linda, California, United States
Nemours/Alfred I DuPont Hospital for Children, Wilmington, Delaware, United States
... and 7 more locations