

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

NCT02235857

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

Key Eligibility Criteria

Inclusion (6)

- A pediatric patient is deemed suitable for inclusion in the study if the patient has FSGS with a GFR ≤ 45 ml/min/1.73 m² 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
- ... and 1 more (see full listing online)

Exclusion (15)

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

Locations (12 total)

Loma Linda University Children's Hospital, Loma Linda, California, United States
Cedars Sinai Medical Center, Los Angeles, California, United States
Nemours/A.I. duPont Hospital for Children, Wilmington, Delaware, United States
... and 9 more locations

<https://clinicaltrials.gov/study/NCT02235857>

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