A Feasibility Study to Evaluate Safety and Probable Benefit of the Eclipse XL1 System for Distraction Enterogenesis in Adult and Pediatric Patients With Short Bowel Syndrome

Status: RECRUITING

Eligibility Criteria

Sex: ALL
Age: 3 months to 65 years old
Healthy Volunteers: This study is NOT accepting healthy volunteers
Inclusion Criteria:

- Subject has short bowel syndrome, defined as 50% or less of expected bowel length based on subject age and/or height, and measured at the time of the subject's prior intestinal resection.
- Minimum residual bowel length of 3 cm.
- Male or female patients aged 3 mo to 65 years inclusive
- The subject, parent or legal guardian of the subject is able to read, understand, and is willing to provide informed consent.
- The subject or parent or legal guardian of the patient is able to understand the requirements of the study and is willing to bring the subject to all clinic visits and complete all study related procedures (as determined by the investigator).

Exclusion Criteria:

- Ultra-short bowel syndrome defined as less than 3 cm of bowel length.
- Diagnosed Inflammatory bowel disease-unclassified (not Crohn's or ulcerative colitis)
- Evidence of active or prior Crohn's disease.
- Primary intestinal failure (i.e., without loss or resection of intestinal tissue).
- Coagulopathy, as defined by INR > 1.4 or platelets < 100.
- Known immunocompromised status including, but not limited to, individuals who have undergone organ transplantation, chemotherapy or radiotherapy within the past 12 months, who have clinically significant leukopenia, who are positive for the human immunodeficiency virus (HIV) or whose immune status makes the subject a poor candidate for clinical trial participation in the opinion of the Investigator.
- Subject is determined by the investigator to be unsuitable for participation in this trial for any reason.

Conditions & Interventions

Interventions:
DEVICE: Distraction Enterogenesis in Adult Patients with Short Bowel Syndrome
Conditions:
Short Bowel Syndrome
Keywords:
short bowel syndrome, intestinal failure, Necrotizing enterocolitis, short gut, intestinal volvulus, intestinal atresia

More Information

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