

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

NCT05535361

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| Status | RECRUITING |
| Phase | Not Applicable |
| Sponsor | Eclipse Regeneration, Inc. |
| Enrollment | 40 participants |

Plain Language Summary

This study is testing a device called the Eclipse XL1 System for people with short bowel syndrome (SBS) — a condition where much of the small intestine is missing or has been removed, making it very hard to absorb nutrients. The device works by gradually stretching the remaining intestine to help it grow longer and absorb more nutrients, reducing the need for IV nutrition.

****You may be eligible if:****

- You have short bowel syndrome, meaning you have 50% or less of the expected bowel length for your age or height
- You have at least 3 cm of remaining bowel
- You are between 3 months and 65 years old
- You or your legal guardian can give informed consent and attend all study visits

****You may NOT be eligible if:****

- You have less than 3 cm of remaining bowel (ultra-short bowel syndrome)
- You have Crohn's disease or another inflammatory bowel disease
- You have active serious infections or other conditions that make surgery unsafe

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (5)

- 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 (7)

- 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.

... and 2 more (see full listing online)

<https://clinicaltrials.gov/study/NCT05535361>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).

Locations (6 total)

Lucile Packard Children's Hospital Stanford, Palo Alto, California, United States
University of California San Francisco, San Francisco, California, United States
Stanford University School of Medicine, Stanford, California, United States
... and 3 more locations