

Open-Label Pilot Study With Crofelemer in Patients With Short Bowel Syndrome

NCT06326645

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Lindsey Russell, MD
Enrollment	6 participants

Key Eligibility Criteria

Inclusion (14)

- Patients must understand and provide written informed consent before they can participate in the study. They must understand the study procedures of the trial and be willing to complete the required assessments;
 - Male and female patients aged ≥ 18 years;
 - SBS patients without colon in continuity;
 - Patients with history of SBS resulting in intestinal failure caused by a major intestinal resection (e.g., injury, cancer, Crohn's disease, vascular disease, volvulus, intussusceptions or other causes). Diagnosis of SBS will be defined as remaining small bowel excluding colon in continuity and considered stable with regard to parenteral support (PS) need. Intestinal failure will be defined according to the recommendations of the American Society of Parenteral and Enteral Nutrition (ASPEN), i.e. a reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes, such that intravenous (IV) supplementation is required to maintain health and/or growth;
 - At least 6 months elapsed since last surgical bowel resection;
- ... and 9 more (see full listing online)

Exclusion (27)

- Body mass index (BMI) < 17.5 or > 30 kg/m²;
 - Presence of clinically significant intestinal adhesions and/or chronic abdominal pain that can interfere with the conduct of the study;
 - Presence of confirmed active infection, temperatures $> 100^{\circ}$ Fahrenheit, or symptoms of an upper respiratory infection
 - Patients with Radiological (Radiography and/or CT) signs of significant bowel dilatation or pseudo-obstruction;
 - Active Crohn's disease as evaluated by standard procedures employed by the investigator;
- ... and 22 more (see full listing online)

Locations (1 total)

Cleveland Clinic Main Campus, Cleveland, Ohio, United States

<https://clinicaltrials.gov/study/NCT06326645>

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