

Safety and Efficacy of Crofelemer in Adult Patients With Short Bowel Syndrome and Intestinal Failure (SBS-IF) Without Colon-in-continuity (CIC)

NCT06904872

Status	RECRUITING
Phase	Phase 2
Sponsor	Napo Therapeutics, S.p.A.
Enrollment	18 participants

Key Eligibility Criteria

Inclusion (17)

- Patients will be enrolled in the study if they meet all the following criteria:
- Patients must understand and provide written informed consent before they can participate in the study. They must understand the study procedures and be willing to complete the required assessments;
- Male and female patients aged e 18 years;
- SBS patients with intestinal failure and without colon-in-continuity who are not eligible or not willing to receive an approved marketed GLP-2;
- 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) without colon-in-continuity (patients with duodenostomy, Jejunostomy or Ileostomy). Intestinal failure will be defined according to the recommendations of the European Society for Clinical Nutrition and Metabolism (ESPEN), 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. ^{*}Patients with history of cancer, should be in remission for the last 6 months and with not ongoing anticancer therapy (long-term hormonal therapy is allowed).

... and 12 more (see full listing online)

Exclusion (24)

- Patients cannot be enrolled in the study if they meet any of the following criteria:
- Body mass index (BMI) $\lt 17.5$ or $\gt 30$ kg/m²;
- Presence of clinically significant intestinal adhesions and/or chronic abdominal pain that can interfere with the conduct of the study;
- Patients with radiological (Radiography and/or CT) signs of bowel dilatation or pseudo-obstruction;
- Active Crohn's disease as evaluated by standard procedures employed by the investigator;

... and 19 more (see full listing online)

Locations (8 total)

Universitätsklinik RWTH, Aachen, Germany
Charité Universitätsmedizin, Berlin, Germany
Universitätsklinikum, Essen, Germany
... and 5 more locations

<https://clinicaltrials.gov/study/NCT06904872>

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