

# A 90 Day, Phase 3, Open Labeled Exploratory Study of RELiZORB

NCT03530852

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<b>Status</b>	RECRUITING
<b>Phase</b>	Not Applicable
<b>Sponsor</b>	Boston Children's Hospital
<b>Enrollment</b>	32 participants

## Key Eligibility Criteria

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### Inclusion (11)

- Male or female patients, ages 2 years to 18 years, inclusive.
- Diagnosed with SBS, as determined by medical history and PN dependence (i.e. need for PN for >60 days after intestinal resection or a bowel length <25% of expected).
- Congenital or acquired gastrointestinal disease requiring surgical intervention that has occurred at least 3 months prior to screening.
- Patient is on parenteral lipid and at least 30% of daily caloric and fluid intake has been provided by PN for a least 6 months prior to screening
- Stable PN nutrition requirement, determined by less than 5% reduction in PN nutrition calories for at least 1 month prior to screening, or at the discretion of the investigator.

... and 6 more (see full listing online)

### Exclusion (14)

- Other causes of chronic liver disease other than SBS (i.e., hepatitis C, cystic fibrosis, biliary atresia, alpha 1 anti-trypsin deficiency, and Alagille syndrome).
- The patient has had a bowel lengthening procedure, including but not limited to, a STEP procedure.
- Any serum triglyceride concentration >400 mg/dL at screening.
- Pancreatic insufficiency as defined as the use of pancreatic enzymes within 30 days prior to screening.
- Evidence of untreated intestinal obstruction or active stenosis, as determined by the investigator.

... and 9 more (see full listing online)

## Locations (1 total)

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Boston Children's Hospital, Boston, Massachusetts, United States