A Study of Teduglutide in Chinese Adults With Short Bowel Syndrome

NCT06973304

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	13 participants

Key Eligibility Criteria

Inclusion (9)

- Males or females 18 years of age or older at the time of signing the informed consent.
- Intestinal failure due to SBS as a consequence of major intestinal resection (example, due to injury, volvulus, vascular disease, cancer, Crohn's disease).
- Has undergone intestinal resection resulting in at least 12 continuous months of PS dependency prior to signing the informed consent.
- Requires PS at least 3 times per week or at least 4 liters per week during the 2 weeks prior to baseline to meet caloric, fluid, or electrolyte needs due to ongoing malabsorption.
- Has a stable PS requirement for at least 4 consecutive weeks immediately prior to the start of teduglutide treatment. Stability is defined as follows:

... and 4 more (see full listing online)

Exclusion (25)

- Pregnant or lactating female.
- Participation in a clinical study using an experimental drug within 30 days or 5 half-lives, whichever is longer, prior to screening, or concurrent participation in any other clinical study.
- Use of glucagon-like peptide (GLP)-2 or human growth hormone or analogs of these hormones within the past 6 months prior to the baseline visit.
- Use of octreotide, GLP-1 analogs, or dipeptidyl peptidase-4 inhibitors within 30 days prior to the baseline visit.
- Previous use of teduglutide.

... and 20 more (see full listing online)

Locations (4 total)

Beijing Tsinghua Changgung Hospital, Changping, Beijing Municipality, China
Peking Union Medical College Hospital, Dongcheng, Beijing Municipality, China
Affiliated Jinling Hospital, Medical School of Nanjing University, Nanjing, Jiangsu, China
... and 1 more locations