

A Study of Teduglutide in Chinese Children and Teenagers With Short Bowel Syndrome

NCT07319832

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| Status | RECRUITING |
| Sponsor | Takeda |
| Enrollment | 12 participants |

Key Eligibility Criteria

Inclusion (5)

- Children and adolescents greater than or equal to (\geq)1 through 17 years of age at Day 1 (D1).
- Documented diagnosis of SBS.
- Received or plan to receive Teduglutide treatment for a minimum of 24 weeks.
- Stable PN/IV support, defined as inability to significantly reduce PN/IV support, usually associated with minimal or no advance in enteral feeds (i.e., 10% or less change in PN or advance in feeds) for at least 3 months prior to D1, as assessed by the investigator. Transient instability for events such as interruption of central access or treatment for sepsis is allowed if the PN/IV support returns to within 10% of baseline prior to the event.
- Informed consent obtained from the patient aged 8 to 17 years and their guardians, while informed consent from the guardians for participants under 8 years old, unless waived by the Institution's Ethics Committee.

Exclusion (17)

- Participants who are not expected to be able to advance oral or tube feeding regimens.
- Serial Transverse Enteroplasty (STEP) or any other bowel lengthening procedure performed within 3 months prior to baseline.
- Known clinically significant untreated intestinal obstruction contributing to feeding intolerance and inability to reduce PS.
- Evidence of clinically significant obstruction on upper GI series done within 6 months prior to baseline.
- Previous use of octreotide or Dipeptidyl peptidase-4 (DPP-4) inhibitors within 3 months prior to baseline.

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

Locations (4 total)

Guangzhou Women And Children's Medical Center, Guangzhou, Guangdong, China

Shanghai Children's Hospital, Shanghai, Shanghai Municipality, China

Xinhua Hospital Affiliated to Shanghai Jiao Tong University School of Medicine, Shanghai, Shanghai Municipality, China

... and 1 more locations