

Efficacy and Safety of PJ009 in Patients With Short Bowel Syndrome Requiring Parenteral Nutrition

NCT06512584

Status	RECRUITING
Phase	Phase 3
Sponsor	Chongqing Peg-Bio Biopharm Co., Ltd.
Enrollment	72 participants

Key Eligibility Criteria

Inclusion (7)

- Male and female aged e 14 years;
- SBS patients dependent on PN/IV support for at least 6 consecutive months due to major intestinal resection;
- At least 3 PN/IV support sessions per week are required 1 week before screening or 2 weeks before baseline;
- Be on stable PN/IV support for at least 4 consecutive weeks before administration;
- For subjects with a history of Crohn's disease (CD), clinical assessment of remission for at least 12 weeks prior to administration;
- ... and 2 more (see full listing online)

Exclusion (24)

- Have used teduglutide in the past or may be allergic to teduglutide or its components;
- Have used natural GLP-2 or its analogs, human growth hormone or its analogs within 6 months before screening;
- Have used glutamine, octreotide, GLP-1 analogs or dipeptidyl peptidase-IV inhibitors within 30 days before screening;
- With active Crohn's disease or those who need to change biological therapy within 6 months before screening;
- With active inflammatory bowel disease (IBD) or IBD patients who have received immunosuppressant therapy changes in the past 3 months;
- ... and 19 more (see full listing online)

Locations (8 total)

Beijing Tsinghua Changgung Hospital, Beijing, Beijing Municipality, China
Chongqing General Hospital, Chongqing, Chongqing Municipality, China
The Sixth Affiliated Hospital of Sun Yat-sen University, Guangzhou, Guangdong, China
... and 5 more locations

<https://clinicaltrials.gov/study/NCT06512584>

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