

# A Study of Lianxiaxiaopi Granules in the Treatment of Postprandial Distress Syndrome

NCT06696261

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Status	RECRUITING
Phase	Phase 3
Sponsor	Tasly Pharmaceutical Group Co., Ltd
Enrollment	342 participants

## Key Eligibility Criteria

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### Inclusion (7)

- Age 18 to 65 years old (including boundary value), gender is not limited;
- meet the diagnostic criteria for postprandial distress syndrome (Rome IV.);
- Meet the syndrome differentiation standards of Traditional Chinese Medicine for cold and heat miscellaneous syndromes;
- NRS score of at least one symptom of postprandial distress syndrome (postprandial fullness, discomfort, early satiety) in the screening period and baseline period 4 points; and did not have moderate/severe epigastric pain syndrome (mid-epigastric burning sensation and mid-upper quadrant pain both < 4 points);
- Those who did not have organic abnormal changes in the results of gastroscopy (including no abnormalities in gastroscopy, chronic non-atrophic gastritis/chronic superficial gastritis with erythema grade I and/or erosion that was flat and only grade I);
- ... and 2 more (see full listing online)

### Exclusion (13)

- Those who have undergone Helicobacter pylori eradication treatment within 6 months before screening;
- Gastric mucosal erythema grade II or above, erosion is bulge or grade II or above, or accompanied by bleeding, bile reflux, e 3 inflammatory polyps and other manifestations, or combined with pathological diagnosis of chronic atrophic gastritis, hyperplastic polyps, glandular polyps, etc.; or those who have been clearly diagnosed with dyspepsia caused by organic diseases of the digestive system, such as digestive tract tumors, hepatobiliary and pancreatic diseases, inflammatory bowel diseases, etc.; or those who have other diseases that affect the evaluation of dyspepsia-related symptoms in the past, such as reflux esophagitis, peptic ulcer, gastrointestinal bleeding, intestinal obstruction, etc.;
- Those who have been diagnosed with systemic diseases that seriously affect the function of the digestive tract, such as hyperthyroidism or hypothyroidism, diabetes, chronic renal insufficiency, connective tissue diseases, etc.;
- Patients with severe cardiovascular and cerebrovascular, liver, lung, kidney, blood or systemic diseases that affect their survival; or patients with severe mental illness in the past, such as moderate or severe depression/anxiety/bipolar disorder, etc.;
- Those who have a history of major abdominal surgery in the past, which may affect gastrointestinal function (except for appendectomy, cesarean section, endoscopic colon polyp resection and other surgeries that do not affect digestive function);
- ... and 8 more (see full listing online)

## Locations (18 total)

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Guang'anmen Hospital, China Academy of Chinese Medical Sciences, Beijing, Beijing Municipality, China  
Gansu Provincial Hospital of Traditional Chinese Medicine, Lanzhou, Gansu, China  
The First Affiliated Hospital of Guizhou University of Traditional Chinese Medicine, Guiyang, Guizhou, China  
... and 15 more locations

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<https://clinicaltrials.gov/study/NCT06696261>

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