ISRCTN59688916 https://doi.org/10.1186/ISRCTN59688916

A study testing whether a traditional herbal medicine can improve constipation and gut health in people with irritable bowel syndrome

Submission date
19/03/2026

Recruitment status
No longer recruiting

Registration date
28/03/2026

Overall study status
Completed

Last Edited
20/03/2026

Condition category
Digestive System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English summary of protocol

Background and study aims
Irritable bowel syndrome is a common condition that affects the digestive system and can cause symptoms such as constipation, abdominal pain, and bloating. Current treatments do not work well for everyone. There is growing interest in whether traditional herbal medicines can improve symptoms by affecting gut health and the bacteria living in the intestines. This study aims to find out whether a herbal medicine called Zhishi Daozhi Pill can improve bowel habits and overall symptoms in people with constipation-predominant irritable bowel syndrome.

Who can participate?
Adults aged 18 to 65 years with constipation-predominant irritable bowel syndrome.

What does the study involve?
Participants are randomly assigned to receive either the herbal medicine or a placebo (a look-alike inactive treatment). Neither the participants nor the researchers know which treatment each person receives during the study. The treatment is taken by mouth twice daily for 12 weeks. Participants record their bowel habits and symptoms, attend regular study visits, and provide stool samples for analysis.

What are the possible benefits and risks of participating?
Participants may experience improvement in their symptoms, but this cannot be guaranteed. The herbal medicine has been used traditionally and is expected to be safe, but mild side effects such as digestive discomfort may occur. There is also a small inconvenience related to study visits and sample collection.

Where is the study run from?
The Taixing People’s Hospital in Jiangsu Province, China.

When is the study starting and how long is it expected to run for?
October 2025 to February 2026.

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr Shaohua Luo at Taixing People's Hospital (email available upon request).

Contact information

Type(s)
Principal investigator, Public

Contact name
Dr Shaohua Luo

Contact details
Department of Traditional Chinese Medicine, Taixing People's Hospital, No. 1 Changzheng Road
Taixing
China
225400
+8615195272322
xngbbamm@163.com

Type(s)
Scientific, Principal investigator

Contact name
Dr Lei Chen

Contact details
Department of Gastroenterology, Taixing People's Hospital, No. 1 Changzheng Road
Taixing
China
225400
+8615195272322
cl_1123@163.com

Additional identifiers

Study information

Scientific Title
Adults with constipation-predominant irritable bowel syndrome receiving Zhishi Daozhi Pill compared with placebo for improving bowel movements and symptom severity in a randomized double-blind controlled trial

Acronym
ZDP-IBS

Study objectives

The primary objective of this study is to evaluate whether Zhishi Daozhi Pill improves bowel function and overall symptom severity in adults with constipation-predominant irritable bowel syndrome compared with placebo. Secondary objectives are to assess the effects of the intervention on stool consistency, abdominal symptoms, quality of life, and safety. Exploratory objectives are to investigate whether clinical improvements are associated with changes in gut microbiota composition and metabolite profiles, including short-chain fatty acids, bile acids, and neuroactive compounds.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 30/09/2025, Medical Ethics Committee of Taixing People’s Hospital (No. 1 Changzheng Road, Taixing City, Jiangsu Province; No. 98 Runtai South Road, Taixing City, Taixing, 225400, China; +8652387656024; kjk6024@163.com), ref: LS2025062

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Placebo

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Treatment of constipation-predominant irritable bowel syndrome in adults

Interventions
Participants are randomised in a 1:1 ratio to receive either Zhishi Daozhi Pill or a matched placebo using a computer-generated randomisation schedule with allocation concealment. The intervention group receives Zhishi Daozhi Pill capsules containing standardised herbal extracts, administered orally at a dose of 6 g twice daily for 12 weeks. The control group receives identical placebo capsules administered at the same frequency and duration. Both participants and study personnel are blinded to treatment allocation throughout the study period. Concomitant use of stable fibre supplements is permitted, while initiation of probiotics, prebiotics, antibiotics, or prescription laxatives is prohibited. Rescue medication with polyethylene glycol is allowed in limited amounts and is recorded.

Intervention Type

Supplement

Primary outcome(s)
1. Change in complete spontaneous bowel movements per week measured using Patient-reported daily bowel diary at Week 12

2. Change in symptom severity measured using Irritable Bowel Syndrome Severity Scoring System at Week 12

Key secondary outcome(s)
1. Stool consistency measured using the Bristol Stool Form Scale at 12 weeks

2. Bloating severity measured using a Visual Analogue Scale at 12 weeks

3. Quality of life measured using Irritable Bowel Syndrome Quality of Life questionnaire at 12 weeks

4. Adverse events measured using clinical assessment and laboratory testing at 12 weeks

Completion date
28/02/2026

Eligibility

Key inclusion criteria
1. Adults aged 18 to 65 years.
2. Diagnosis of constipation-predominant irritable bowel syndrome according to Rome IV criteria.
3. Irritable Bowel Syndrome Severity Scoring System score of 175 or higher at screening.
4. Fewer than 3 complete spontaneous bowel movements per week during the 2-week run-in period.
5. Ability and willingness to provide written informed consent.

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
65 Years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Presence of organic gastrointestinal disease such as inflammatory bowel disease or colorectal cancer.
2. History of gastrointestinal surgery affecting bowel motility.
3. Major psychiatric illness.
4. Pregnancy or breastfeeding.
5. Use of antibiotics, probiotics, prebiotics, or laxatives within 4 weeks prior to enrolment.
6. Participation in another interventional clinical trial.
7. Clinically significant comorbid conditions that could interfere with study participation.

Date of first enrolment
01/10/2025

Date of final enrolment
15/12/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Taixing People's Hospital

ROR
https://ror.org/02ez0zm48

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available