ISRCTN15490908 https://doi.org/10.1186/ISRCTN15490908

A study on the efficacy of traditional chinese patent medicines for constipation

Submission date 23/12/2025	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol
Registration date 31/12/2025	**Overall study status** Ongoing	[_] Statistical analysis plan [_] Results
Last Edited 29/12/2025	**Condition category** Digestive System	[_] Individual participant data [X] Record updated in last year

Plain English summary of protocol

Background and study aims
As a common functional gastrointestinal disease, constipation affects about 20% of the general population worldwide and has a serious negative impact on the quality of life of patients. Qihuangtongmi soft capsule has been used in the treatment of constipation for many years, but the evidence-based medicine (EBM) level is low and the strong evidence is insufficient. The aim of this study was to evaluate the efficacy of qihuangtongmi soft capsule in the treatment of constipation.

Who can participate?
Adults aged 18-70 years with a diagnosis of constipation.

What does the study involve?
Participants were divided into two allocation groups, the treatment group received Qi Huang Tong mi soft capsules, the control group received Maren Runchang soft capsules.

What are the possible benefits and risks of participating?
Participating in the study may improve symptoms of constipation, and the information will help researchers and doctors better treat other patients with similar conditions in the future. However, there are potential risks. The study drug may have side effects that the team will closely monitor.

Where is the study run from?
The trial is conducted at three clinical trial centers. The leading unit is Affiliated Hospital of Shandong University of Traditional Chinese Medicine. The study is sponsored by Pharmaceutical (Zibo) Co., Ltd.

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

Who is funding the study?
Investigator initiated and funded.

Who is the main contact?
Dr Yang Wang, wangyang@cnrc.cn

Contact information

Type(s)
Public, Scientific

Contact name
None Jinkai Xu

Contact details
No. 17 Lanyan Avenue, High-Tech Zone, Zibo City, Shandong Province
Zibo
China
255000
+86 18810689823
xujinkai@cnrc.cn

Type(s)
Principal investigator

Contact name
Dr Yang Wang

Contact details
No. 17 Lanyan Avenue, High-Tech Zone, Zibo City, Shandong Province
zibo
China
255000
15901133922
wangyang@cnrc.cn

Additional identifiers

Study information

Scientific Title
Clinical study on the efficacy, safety, and cost-effectiveness of Qihuangtongmi Soft Capsules for constipation treatment

Study objectives
Using MaRen Runchang Soft Capsules as the control medication, this study investigates the effects of Qihuang Tongmi Soft Capsules on changes in the frequency of complete spontaneous bowel movements and stool consistency scores, aiming to evaluate its efficacy in treating constipation.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 10/12/2025, Ethics Committee of the Affiliated Hospital of Shandong University of Traditional Chinese Medicine (No. 16369 Jingshi Road, Jinan, Shandong Province, jinan, 250014, China; +86 0531-68616733; sdzyydxfsyyllwyh@163.com), ref: AF/SC-08/03.0

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Constipation

Interventions
Experimental Group: Qi Huang Tong Mi Soft Capsules, taken orally 30 minutes after meals, 3 capsules per dose, twice daily; treatment for 7 days;
Control Group: Ma Ren Run Chang Soft Capsules, taken orally, 8 capsules per dose, twice daily; treatment for 7 days;

A random allocation sequence will be generated using R statistical software with a 1:1 allocation ratio. The sequence will be implemented using sequentially numbered, sealed envelopes.
A third party will assign participants to either group A or group B according to the random numbers, and the allocation will be concealed from the investigators responsible for patient recruitment. The randomization code, including the initial seed and block size, as well as the corresponding treatments for groups A and B, will be documented.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Qi Huang Tong Mi Soft Capsules, Ma Ren RunChang Soft Capsules

Primary outcome(s)

1. Complete Spontaneous Bowel Movement (CSBM) frequency measured using the patient-reported daily CSBM response rate at baseline period and after 1 week (end of treatment)

Key secondary outcome(s))
1. Remedial drug (Keseru) usage measured using a reported record at all times until the end of treatment at one time point

2. Changes in fecal trait scores (with reference to Bristol fecal typing criteria) measured using the Bristol Stool Chart at daily until the end of treatment

Completion date
16/12/2026

Eligibility

Key inclusion criteria
1. Meets Western medical diagnostic criteria for constipation
2.Meets Traditional Chinese Medicine diagnostic criteria for heat-type constipation
3. No constipation medication taken within 2 weeks prior to enrollment; fewer than 3 spontaneous bowel movements per week prior to enrollment
4.Aged between 18 and 70 years, inclusive, any gender
5.Voluntarily participate and sign the informed consent form after understanding the full trial process

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 years

Upper age limit
70 years

Sex
All

Total final enrolment
0

Key exclusion criteria
1. Patients with severe primary diseases or malignancies affecting the heart, lungs, kidneys, brain, hematopoietic system, endocrine system, etc.
2.Patients with known allergies to any drug components or those with an allergic constitution (e.g., allergic to two or more drugs or foods)
3.Constipation caused by intestinal stricture due to organic intestinal lesions (e.g., obstructive diseases, gastrointestinal tumors, inflammatory bowel disease, intestinal tuberculosis) or defecation disorders caused by severe organic anal lesions, as diagnosed by the investigator

4.Patients with drug-related constipation: those who have regularly used medications explicitly indicated to cause constipation in the prescribing information (e.g., antispasmodics, antidiarrheals, nonsteroidal anti-inflammatory drugs) within 4 weeks prior to screening, or who cannot discontinue such medications during the study period
5. Women patients during pregnancy and lactation, male subjects and fertile women subjects who are unwilling or unable to adopt effective contraceptive measures during the trial
6. Participants who have enrolled in other drug clinical trials within 3 months prior to screening
7. Other circumstances deemed inappropriate for participation in this trial by the investigator

Date of first enrolment
17/12/2025

Date of final enrolment
23/12/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Rongchang Pharmaceutical (Zibo) Co., Ltd.

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be available upon request

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Participant information sheet	version 1.2	26/11/2025	29/12/2025	No	Yes