ISRCTN87349615 https://doi.org/10.1186/ISRCTN87349615

Clinical study evaluating the efficacy, safety, and cost-effectiveness of Shu Mi Capsules for constipation treatment

Submission date
13/01/2026

Recruitment status
No longer recruiting

Registration date
15/01/2026

Overall study status
Ongoing

Last Edited
14/01/2026

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
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.There is a special constipation in clinic, and its pathogenesis is related to emotion. This study mainly discusses the curative effect of Shumi capsule on constipation caused by liver qi stagnation.

Who can participate?
Adult patients aged 18 to 65 years who have been diagnosed with constipation and meet the inclusion criteria.

What does the study involve?
This study is a prospective, randomly allocated study. Participants were assigned to two groups: the treatment group received Shu Mi Capsules, while the control group received either Ma Ren Run Chang Soft Capsules or Qi Huang Tong Mi 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 pitfalls. The study drug may have side effects that the team will closely monitor.

Where is the study run from?
This study was conducted at Gansu Provincial Traditional Chinese Medicine Hospital, China.

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

Who is funding the study?
Investigator initiated and funded

Who is the main contact?
Prof Xudong Tian, xytxd@163.com

Contact information

Type(s)
Public, Scientific

Contact name
Ms 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
Prof Xudong Tian

Contact details
No. 418 Guazhou Road, Qilihe District, Lanzhou City, Gansu Province
Lanzhou
China
730050
+86 15002591589
xytxd@163.com

Additional identifiers

Study information

Scientific Title
Clinical study evaluating the efficacy, safety, and cost-effectiveness of Shu Mi Capsules for constipation treatment

Study objectives
This study mainly discusses the curative effect of Shumi capsule on constipation caused by liver qi stagnation.

Ethics approval required
Ethics approval required

Ethics approval(s)

approved 05/11/2025, Ethics Committee of Gansu Provincial Hospital of Traditional Chinese Medicine (No. 418 Guazhou Road, Qilihe District, Lanzhou City, Gansu Province, Lanzhou, 730050, China; +86 0931-2687005; 2650187322@qq.com), ref: 2025-047-01

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:
Shu Mi Capsules, oral administration, taken 30 minutes after lunch and dinner, 6 capsules per dose, twice daily; treatment for 7 days.

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

Primary outcome(s)
1. Complete spontaneous bowel movement (CSBM) response rate after 1 week of treatment measured using data recording the frequency of complete self-bowel movements at at baseline period and after 1 week (end of treatment)

Key secondary outcome(s))
1. Dosage of remedial medicine (Glycerol Enema) measured using data recording the number of times at at any time until the end of treatment

2. Changes in stool consistency measured using the Bristol Stool Chart at baseline, 24 hours and then daily until the end of treatment

Completion date
31/12/2026

Eligibility

Key inclusion criteria
1. Meets Traditional Chinese Medicine diagnostic criteria for constipation
2. Has had fewer than 3 spontaneous bowel movements per week prior to enrollment
3.Aged between 18 and 65 years, inclusive, any gender
4.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
65 years

Sex
All

Total final enrolment
90

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. 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
4. Pregnant or lactating women; male subjects; or female subjects of childbearing potential unwilling or unable to use effective contraception during the trial
5. Participants who have enrolled in other drug clinical trials within 3 months prior to screening
6. Other circumstances deemed inappropriate for participation in this trial by the investigator

Date of first enrolment
12/01/2026

Date of final enrolment
13/01/2026

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

IPD sharing plan summary
Data sharing statement to be made available at a later date