

A clinical study on the treatment of deficiency-type constipation

Submission date 07/01/2026	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 09/01/2026	Overall study status Ongoing	☐ Statistical analysis plan ☐ Results
Last Edited 08/01/2026	Condition category Digestive System	☐ Individual participant data ☒ Record updated in last year

Plain English summary of protocol

Background and study aims

Constipation, as a common functional gastrointestinal disease, affects about 20% of the general population worldwide, causing severe negative impacts on quality of life. Qirong Runchang Oral Liquid and Congrong Tongbian Oral Liquid are both traditional Chinese patent medicines that have been on the market for many years. This study aims to evaluate the effectiveness of these two drugs in treating constipation.

Who can participate?

Adults aged 18 to 75 years with constipation

What does the study involve?

Participants are randomly allocated into two groups:

Research Group 1: Qirong Runchang Oral Liquid, oral administration. 20 ml per dose, three times daily, for 7 days

Research Group 2: Congrong Tongbian Oral Liquid, oral administration. 20 ml once daily for 7 days

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?

Weifang City 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?

1. Ms Jinkai Xu, xujinkai@cnrc.cn
2. Prof. Weiwei Zheng, zhww875061@163.com

Contact information

Type(s)

Public, Scientific

Contact name

Ms Jinkai Xu

Contact details

No. 17 Lanyan Avenue, High-Tech Zone

Zibo

China

255000

+86 (0)18810689823

xujinkai@cnrc.cn

Type(s)

Principal investigator

Contact name

Prof Weiwei Zheng

Contact details

No. 1055 Wei Zhou Road, Kuiwen District

Weifang

China

262600

+86 (0)13792635869

zhww875061@163.com

Additional identifiers

Study information

Scientific Title

A clinical study on the efficacy, safety, and cost-effectiveness of Qirong Runchang Oral Liquid and Congrong Tongbian Oral Liquid in treating deficiency constipation

Study objectives

This study mainly investigates the therapeutic effects of Qirong Runchang Oral Liquid and Congrong Tongbian Oral Liquid on deficiency-type constipation.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 31/10/2025, WEIFANG City Traditional Chinese Medicine Hospital Ethics Committee of Clinical Trials (No. 1055 Wei Zhou Road, Kuiwen District, Weifang, 262600, China; +86 (0)536-8190161; wfszyyie@126.com), ref: 2025--13-02

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

Research Group 1: Qirong Runchang Oral Liquid, oral administration. 20 ml per dose, three times daily, for 7 days

Research Group 2: Congrong Tongbian Oral Liquid, oral administration. 20 ml once daily 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)

Qirong Runchang Oral Liquid, Congrong Tongbian Oral Liquid

Primary outcome(s)

1. Complete spontaneous bowel movements (CSBMs) measured using frequency recorded at baseline and after 1 week (end of treatment)

Key secondary outcome(s)

1. Dosage of remedial medicine (Glycerol Enema) measured using dosage recorded at any time until the end of treatment

2. Stool consistency measured using Bristol Stool Chart at daily until the end of treatment

Completion date

31/12/2026

Eligibility

Key inclusion criteria

1. Meets the diagnostic criteria for constipation in Traditional Chinese Medicine
2. Aged between 18 and 75 years (inclusive), gender
3. Has had fewer than three spontaneous bowel movements in the past week prior to enrollment
4. The subject has understood the trial content and voluntarily signed the informed consent form, and the process of obtaining informed consent complies with GCP regulations

Healthy volunteers allowed

No

Age group

Mixed

Lower age limit

18 Years

Upper age limit

75 Years

Sex

All

Total final enrolment

60

Key exclusion criteria

1. Those with severe primary diseases of the heart, lungs, kidneys, brain, hematopoietic system, endocrine system, etc., or malignant tumors
2. Those with allergies to known drug components or allergic constitutions (e.g., allergies to two or more drugs or foods)
3. Those diagnosed by the investigator as having constipation or severe anal organic lesions caused by intestinal narrowing due to organic intestinal diseases (e.g., obstructive diseases, digestive tract tumors, inflammatory bowel disease, intestinal tuberculosis, etc), leading to defecation disorders
4. Those with drug-related constipation: those who have regularly used medications explicitly stated in the drug instructions to cause constipation (e.g., antispasmodics, antidiarrheals,

nonsteroidal anti-inflammatory drugs) in the 4 weeks prior to screening, or those who cannot discontinue these medications during the study

5. Pregnant and breastfeeding women; male subjects and female subjects of childbearing potential who are unwilling or unable to use effective contraceptive measures during the trial

6. Those who have participated in other drug clinical trials within the past 3 months

7. Other situations deemed unsuitable for participation in this trial by the investigator

Date of first enrolment

06/01/2026

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

The datasets generated during and/or analysed during the current study will be available upon request

IPD sharing plan summary

Available on request