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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 [X] 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
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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; wfszyyiec@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