

Participant information sheet

1. Title of Study

Clinical Study on the Efficacy, Safety, and Cost-Effectiveness of Qihuangtongmi Soft Capsules for Constipation Treatment

2. Version Number and Date

Version 1.2, November 26, 2025.

3. Invitation Paragraph

You are invited to participate in a research study. Before you decide whether or not to participate, it is important for you to understand how this research is being done and what it will involve. Please take time to read the following information carefully and feel free to ask us if you would like to have more information. We would like to stress that you do not have to accept this invitation and should only agree to take part if you want to.

Thank you for reading this.

4. What is the purpose of the study?

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.

5. Why have I been chosen to take part?

This study was conducted in adults aged 18-70 years with a diagnosis of constipation, You meet our criteria, and therefore have been selected.

6. Do I have to take part?

Your participation is voluntary, and you are free to withdraw at any time without explanation and without incurring a disadvantage.

7. What will happen if I take part?

If you are willing to participate in this study, you will have a 50% chance of receiving one of the following two treatment regimens:

In the experimental group, Qihuang Tongmi Soft Capsules were administered by mouth, take 3 capsules twice daily, 30 minutes after meals, for a 7-day course.

In the control group, Maren Runchang Soft Capsules were administered by

mouth, Take 8 capsules twice daily for a 7-day course.

8. Expenses and / or payments

There is no expense or payment for participating in this project.

9. Are there any risks in taking part?

Study participants will undergo regular laboratory examinations to monitor for potential side effects or adverse reactions associated with the medication. Symptoms such as excessive bowel movements or diarrhea will be promptly diagnosed and treated.

10. Are there any benefits in taking part?

Participating in this study may improve your condition, and this study also helps determine which treatment method can more safely and effectively treat other patients with similar conditions to yours.

11. Confidentiality in Clinical Trials

All information about you, including your identity, medical history, medical condition, laboratory test results, and other details, will be kept strictly confidential within the scope permitted by law. Researchers, monitors, and the clinical trial ethics committee may directly access the original medical records of study participants within the authorized scope. Any public reports regarding the results of this study will not disclose your personal information.

12. What if I am unhappy or if there is a problem?

If you are unhappy, or if there is a problem, please feel free to let me know at guchao1983812@163.com.

13. What will happen if I want to stop taking part?

Participants can withdraw at any time without explanation. Results up to the period of withdrawal may be used, if you are happy for this to be done. Otherwise you may request that they are destroyed and no further use is made of them.

14. Who can I contact if I have further questions?

If you have any questions about this study, you can contact researcher Gu Chao, at guchao1983812@163.com, located at 16369 Jingshi Road, Lixia District, Jinan City, Shandong Province.