A Multicenter, Randomized, Double-Blind, Parallel-Controlled Clinical Study of Jianpi Lishi Jiedu Granules for Preventing Postoperative Recurrence of Advanced Colorectal Adenomas

Informed Consent Form (Template)

Dear Patient,

You are invited to participate in a clinical research study. This informed consent document provides information to help you decide whether or not to participate in this study. Please read it carefully. If you have any questions, please ask the investigator responsible for this study.

This study will be conducted jointly at several hospitals, including **Nanjing First Hospital, Nanjing Hospital of Traditional Chinese Medicine, Changzhou Traditional Chinese Medicine Hospital, Kunshan Traditional Chinese Medicine Hospital, and Jiangsu Integrated Traditional Chinese and Western Medicine Hospital**. It is estimated that **376 participants** will voluntarily participate in this study.

This research has been reviewed and approved by the **Ethics Committee of Nanjing First Hospital**, and it is expected that **136 participants** will be enrolled at this center.

If you are willing, please read the following information carefully.

Protocol Title: A Multicenter, Randomized, Double-Blind, Parallel-Controlled Clinical Study of Jianpi Lishi Jiedu Granules for Preventing Postoperative Recurrence of Advanced Colorectal Adenomas

Protocol Version and Date: Version: V1.0; Version Date: February 5, 2026

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Study Center: Nanjing First Hospital

Ethics Approval Number: KY20260305-07

1. Purpose of the Study

Colorectal cancer has a high incidence and mortality rate among malignant tumors worldwide and poses a serious threat to human health. The development of colorectal cancer is a **multi-stage and multi-step process involving interactions between internal and external factors**.

In clinical practice, many patients are diagnosed at **middle or advanced stages**, thereby missing the optimal opportunity for early prevention and treatment of precancerous lesions. Therefore, **early detection and prevention of colorectal cancer are extremely important**.

However, even after removal of colorectal adenomas, **high recurrence rates and possible malignant transformation remain major clinical challenges**. Preventing recurrence of **advanced colorectal adenomas** and reducing the risk of cancer development have become urgent issues in clinical practice.

Currently, there is **no widely recognized effective intervention** to prevent recurrence or malignant transformation after endoscopic removal of colorectal adenomas (especially advanced adenomas). Therefore, exploring safe and effective preventive strategies has become an important focus of clinical research.

Conventional Western medical preventive approaches include **dietary modification and medications such as aspirin**, but their effects are limited and long-term use may cause side effects such as **gastrointestinal bleeding**.

In recent years, **Traditional Chinese Medicine (TCM)** has shown potential in this field. Previous clinical and experimental studies in China suggest that TCM may reduce postoperative recurrence of colorectal adenomas through multiple mechanisms, including:

- regulation of intestinal microbiota balance
- improvement of mucosal immune function
- inhibition of inflammatory responses
- suppression of abnormal cell proliferation

From a TCM perspective, the fundamental pathogenesis of this disease is **“spleen deficiency with internal accumulation of dampness and toxin.”** Therefore, the

therapeutic principle should be **"strengthening the spleen, eliminating dampness, and detoxifying."**

Our previous small-scale study has shown that **Jianpi Lishi Jiedu Granules** can significantly reduce postoperative adenoma recurrence and improve symptoms such as abdominal distension and abdominal pain, with good safety.

Based on these findings, we plan to conduct a **larger and more rigorous clinical study** to further evaluate whether this herbal formula can effectively prevent recurrence of advanced colorectal adenomas and improve patients' quality of life and intestinal health.

This study aims to provide a **safe and effective TCM-based preventive strategy** for patients with colorectal adenomas, fill the gap in high-quality clinical evidence in this field, and provide scientific support for the application of TCM in cancer prevention.

2. Study Procedures and Important Considerations

This study will be conducted at several hospitals including **Nanjing First Hospital**, and approximately **376 patients** who have undergone colorectal adenoma resection and meet the TCM syndrome of **spleen deficiency with damp-toxin accumulation** will be recruited.

If you agree to participate, the study procedures will include the following steps:

(1) Screening and Enrollment

The physician will evaluate whether you meet the eligibility criteria, including:

・medical history review

・physical examination

・necessary laboratory tests

(2) Randomization

If eligible, you will be randomly assigned to one of two groups:

・**Treatment Group:** Jianpi Lishi Jiedu Granules

・**Control Group:** Placebo granules with similar appearance and taste

The assignment is random, and neither you nor your doctor will know which group you are assigned to during the study to ensure objectivity.

(3) Medication and Follow-Up

You will take the study medication for **3 months**, twice daily. There will be **5 study visits** during the study: screening visit, baseline visit (enrollment), month 3, month 6, month 12. During these visits, doctors will assess your health status, record symptoms, and perform examinations.

(4) Number of Visits and Examinations

During the **1-year study period**, you will return to the hospital for follow-up approximately **6–8 times**, including screening and final evaluation. Major examinations include:

a. Blood Tests

A small amount of venous blood (**10–15 mL**) will be drawn each time to examine: blood routine, liver function, kidney function, to ensure medication safety.

b. Urine Sample

Approximately **20 mL of urine** may be collected for routine examination.

c. Stool Sample

A small stool sample (**about 5 g**) may be collected to analyze intestinal microbiota.

d. Colonoscopy

Colonoscopy will be performed at: **6 months and 12 months**, to determine whether adenomas have recurred.

e. Drug Dispensing and Return

During the first **3 months**, you will visit the hospital approximately **every 4 weeks** to: receive medication for the next month, return empty medication bags or unused drugs. This helps investigators assess medication compliance.

(5) Important Notes

a. Participation is voluntary, and you may withdraw at any time without affecting your medical care.
b. During the study, please avoid taking other anti-tumor herbal medicines or medications that may affect adenoma recurrence, such as: aspirin, metformin. If such medications are necessary, please inform your doctor in advance.
c. Blood, urine, and stool samples collected will be used only for this study.
d. If you experience any discomfort during the study, please inform the doctor immediately. Necessary medical care will be provided.

3. Who Can or Cannot Participate

(1) Who Can Participate

You may participate if you meet all of the following conditions:

a. Age 18–80 years, male or female
b. Underwent endoscopic colorectal adenoma resection within the past 2 weeks, confirmed by endoscopy and pathology as advanced colorectal adenoma
c. Meet the TCM syndrome of spleen deficiency with damp-toxin accumulation
d. Provide written informed consent and agree to participate voluntarily

(2) Who Cannot Participate

You cannot participate if any of the following apply:

a. Hereditary polyposis syndromes (familial adenomatous polyposis, serrated polyposis syndrome, Peutz–Jeghers syndrome)
b. Long-term use of aspirin, metformin, probiotics, folic acid, calcium, or vitamin D
c. Bleeding tendency or use of anticoagulant drugs
d. Active inflammatory bowel disease
e. Suspected or confirmed colorectal cancer
f. Pregnancy or breastfeeding
g. Severe allergy or multiple drug allergies
h. Severe heart, brain, lung, liver, kidney disease, or psychiatric illness
i. Currently participating in other clinical trials

4. Risks and Discomforts

All research involves known or unknown risks. Some risks may be mild and temporary, while others may be serious. Known adverse reactions of Jianpi Lishi

Jiedu Granules include: gastrointestinal symptoms (nausea, vomiting, abdominal pain, diarrhea), allergic reactions (rash, itching, swelling), liver or kidney function abnormalities, electrolyte disturbances.

Possible risks related to study procedures include: bruising or bleeding from blood sampling, colonoscopy-related risks such as abdominal discomfort, perforation, infection, anesthesia risks including respiratory depression or hypotension.

This study does not increase the number of colonoscopy procedures beyond standard clinical care.

5. Benefits

Your health condition may improve through participation. Participants will receive: free study medication, TCM symptom evaluation, quality-of-life assessment, potential reduction in adenoma recurrence risk, transportation compensation of 300 RMB. Participants will also receive long-term follow-up and health management from physicians.

6. Financial Information

Participants will receive the study medication **free of charge**. After completing **5 study visits**, participants will receive **300 RMB transportation reimbursement**. No other financial compensation will be provided.

7. Responsibilities of Participants

As a participant, you are expected to: provide accurate medical history information, report any discomfort during the study, avoid prohibited medications, inform investigators if participating in other studies.

8. Privacy Protection

If you participate in this study, your personal information will remain confidential. Your samples will be labeled with study identification numbers rather than your name. Only authorized study personnel may access your information. Government authorities or ethics committees may review study data if necessary. Published results will not disclose your identity.

9. Rights of Participants

If you are injured due to participation in this study, you may receive free treatment and/or compensation. Participation is voluntary. You may withdraw at any time without affecting your medical care. If necessary, investigators may terminate your participation due to: need for other treatments, non-compliance with study protocol, study-related injury, other reasons.

10. Contact Information

Ethics Committee Contact:

Nanjing First Hospital Ethics Committee

Telephone: 025-52271064

Informed Consent Statement

I have read the information in this informed consent form.

I had the opportunity to ask questions and received satisfactory answers.

I understand that participation in this study is voluntary.

I may withdraw from the study at any time without affecting my medical care.

I will receive a signed copy of this informed consent form.

I voluntarily agree to participate in this study.

Participant Signature: _____Date: _____ / _____ / _____

Participant Contact Number: _____

If the participant cannot sign due to lack of legal capacity, a guardian may sign.

Guardian Signature: _____

Relationship to Participant: _____

Reason the participant cannot sign: _____

Contact Information: _____Date: _____ / _____ / _____

Investigator Statement

I have explained this study to the participant and answered all questions.
The participant has voluntarily agreed to participate.

Investigator Signature: _____Date: _____ / _____ / _____

Investigator Telephone: _____