

**Clinical Efficacy and Safety of Jingfang Granules in Treating
Diarrhea-Predominant Irritable Bowel Syndrome with Cold-Dampness
Disturbing Spleen Syndrome
Informed Consent Form**

Dear Patient:

We would like to invite you to participate in a clinical study. This informed consent form provides you with information to help you decide whether to take part. Please read it carefully, and if you have any questions, ask the investigator responsible for this study.

This study will be conducted at Nanjing First Hospital, and it is estimated that 106 research participants will voluntarily join. The study has been reviewed and approved by the Ethics Committee of Nanjing First Hospital, and 106 participants are expected to be enrolled at this center.

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

Protocol Title: Clinical Efficacy and Safety of Jingfang Granules in Treating Diarrhea-Predominant Irritable Bowel Syndrome with Cold-Dampness Disturbing Spleen Syndrome

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I. Research Purpose

Irritable bowel syndrome with diarrhoea (IBS-D) is a common functional bowel disorder of the digestive system and one of the important clinical subtypes of irritable bowel syndrome (IBS). It has a high prevalence and is mainly manifested as abdominal pain and diarrhoea, characterized by persistent or intermittent episodes. Pathophysiological factors include visceral hypersensitivity, abnormal intestinal motility, altered intestinal barrier function, immune activation, gut microbiota dysbiosis, and genetic factors. Currently, Western medicine treatment for IBS-D mainly focuses on symptomatic intervention, commonly using antispasmodics, serotonin-related agents, antidiarrheal agents, intestinal microecological preparations, and antidepressants.

Based on the clinical characteristics of IBS-D, it can be categorized under traditional Chinese medicine concepts such as “xie xie” (diarrhea), “da chang xie” (large intestine diarrhea), “ru xie” (soggy diarrhea), “sun xie” (lenteric diarrhea), and “abdominal pain”. Patients with IBS-D often suffer from externally contracted cold-dampness or internal injury from raw and cold foods, which directly impairs spleen yang in the middle energizer. This leads to the internal generation of cold-dampness that obstructs qi movement, resulting in the pattern of cold-dampness encumbering the spleen. Cold congealing causes qi stagnation with contraction and spasm, while dampness turbidity is viscous and lingering, causing the condition to be protracted. The combination of these two factors renders the disease prolonged, recurrent, and difficult to cure, making it a favorable entry point for TCM

intervention.

Jingfang Granules, a traditional classical formula, is a modern Chinese medicine preparation derived from "Jingfang Baidu Powder." It is composed of 11 herbal medicines: Jingjie (*Schizonepetae Herba*), Fangfeng (*Saposhnikoviae Radix*), Qianghuo (*Notopterygii Rhizoma et Radix*), Duhuo (*Angelicae Pubescentis Radix*), Chaihu (*Bupleuri Radix*), Qianhu (*Peucedani Radix*), Chuanxiong (*Chuanxiong Rhizoma*), Zhiqiao (*Aurantii Fructus*), Fuling (*Poria*), Jiegeng (*Platycodonis Radix*), and Gancao (*Glycyrrhizae Radix*). This formula has traditionally been used for the common cold caused by external contraction of wind-cold-dampness pathogens, with the effects of inducing sweating to release the exterior, dispersing wind, and eliminating dampness. However, this prescription also embodies the therapeutic method of "sailing against the current to rescue the boat," which can raise clear yang, disperse pathogenic qi, and stop diarrhea. Ancient physicians adeptly employed it to treat intestinal wind bleeding. In this formula, the sovereign herbs Jingjie and Fangfeng, acrid and warm in nature, excel at expelling wind and dispersing cold, transforming dampness and invigorating the spleen, directly targeting the etiology of cold-dampness encumbering the spleen, and are particularly effective at relieving the damp turbidity obstructing the middle energizer. Qianghuo and Duhuo serve as minister herbs, assisting the sovereigns in their ascending, dispersing, and outthrusting actions, both driving out exterior cold and transforming interior dampness. Chaihu and Qianhu are paired, one ascending and one descending, to smooth and regulate the qi dynamic of the triple energizer. Chuanxiong invigorates blood, moves qi, and alleviates pain, combined with Zhiqiao to break stagnation and relieve distension. Fuling is added as an adjuvant to fortify the spleen and percolate dampness, guiding water-dampness to drain through urination. Jiegeng diffuses the lung to "lift the lid off the teapot," aiding qi transformation and facilitating the separation and discharge of water-dampness. Gancao harmonizes all the medicinals while simultaneously protecting the middle region. The entire formula works synergistically to release the exterior and vent pathogens, diffuse and smooth qi movement, warm and transform water-dampness, and raise the clear while descending the turbid. Its composition is highly compatible with the core pathogenesis of the cold-dampness encumbering the spleen pattern in IBS-D, which is characterized by internal invasion of cold-dampness, suppression of spleen yang, and stagnation of qi movement.

Based on the traditional Chinese medicine theory of "treating different diseases with the same therapy," it can be inferred that Jingfang Granules are a potentially effective drug for treating the cold-dampness encumbering the spleen pattern in irritable bowel syndrome with diarrhoea (IBS-D). This study aims to evaluate the efficacy and safety of Jingfang Granules in treating IBS-D with the cold-dampness encumbering the spleen pattern, to explore its potential mechanisms of action, and thus to provide new drug options and evidence-based medical evidence for the clinical treatment of IBS-D, as well as to improve patients' quality of life.

2. Study Process and Precautions

2.1 How many people will participate in this study?

It is estimated that 106 subjects will participate in this study at our hospital.

2.2 Study Procedures

If you agree to participate in this study, please sign this informed consent form.

Before you are enrolled in the study, the doctor will ask about and record your basic information and medical history. If you meet the eligibility criteria, you will be randomly assigned in a 1:1 ratio to either the experimental group or the control group. The experimental group will receive Jingfang Granules (15 g per sachet, one sachet each time, three times daily, for 4 weeks), and the control group will receive Trimebutine Maleate Tablets (100 mg per tablet, one tablet each time, three times daily, for 4 weeks).

Both regimens are intended for the treatment of irritable bowel syndrome with diarrhoea (IBS-D) presenting with the cold-dampness encumbering the spleen pattern. You will need to take Jingfang Granules or Trimebutine Maleate Tablets orally. It is also recommended that you avoid raw, cold, high-fat, spicy, and irritating foods, as well as the intake of alcohol, coffee, and tea; engage in appropriate physical activity; and maintain a pleasant state of mind.

Before treatment begins, after treatment ends, and during the follow-up period, you will need to visit Nanjing First Hospital to work with the study physician to establish a medical record file and complete case report forms. We will collect your general information, history of present illness, past medical history, vital signs, medication adherence, concomitant medications, adverse events, and assessments including the IBS-SSS (Irritable Bowel Syndrome Severity Scoring System), Bristol Stool Form Scale, TCM pattern scores, IBS-QOL (Irritable Bowel Syndrome Quality of Life) scale, and PRO (Patient-Reported Outcomes) scale. Before treatment begins and after treatment ends, you will need to cooperate with the physician for an electrocardiogram (ECG) examination, and a professional will draw venous blood from your arm for routine blood tests, blood biochemistry, routine urine tests, routine stool tests, and serum biomarker tests—twice in total.

2.3 How long will this study last?

The study will last for a total of 16 weeks, with a treatment period of 4 weeks. There will be 3 visits during the study. You will need to visit Nanjing First Hospital to have your basic information and disease-related data recorded by the study physician before treatment, after treatment (Day 28), and at Week 16. Before treatment and after treatment (Day 28), a professional will draw venous blood from your arm to assess your condition. Please practice contraception during the treatment period. You may choose to withdraw from the study at any time. However, if you decide to withdraw during the study, we encourage you to discuss it with your physician first. If you experience a serious adverse event, or if your study physician believes that continuing in the study is not in your best interest, he/she will decide to withdraw you from the study. Your withdrawal will not affect your normal medical treatment or rights. If you withdraw from the study for any reason, you may be asked about your participation in the study. If deemed necessary by the physician, you may also be asked to undergo laboratory tests and a physical examination.

2.4 Information Collected in the Study

During this study, your examination results (routine blood tests, blood biochemistry, routine urine tests, routine stool tests, serum biomarkers, and electrocardiogram) and disease-related data (general information, history of present illness, past medical history, vital signs, medication adherence, concomitant medications, adverse events, the IBS-SSS scale, the Bristol Stool Form Scale, TCM pattern scores, the IBS-QOL scale, and the PRO scale) will be collected.

III. Who Can / Cannot Participate

1. You may participate if you meet the following criteria:

(1) Meet the Western medicine diagnostic criteria for IBS-D (IBS symptoms persisting for ≥ 6 months, and meeting the Rome IV criteria in the last 3 months) and the TCM diagnostic criteria for the cold-dampness encumbering the spleen pattern.

(2) Aged between 18 and 65 years, regardless of gender.

(3) Baseline IBS-SSS score ≥ 75 .

(4) Have not used any medication for IBS for at least 1 week prior to entering treatment.

(5) Be informed as a subject and voluntarily sign the informed consent form.

2. You may not participate if you have any of the following conditions:

(1) Patients with severe cardiovascular, respiratory, hepatic, renal, or other major organ diseases, diabetes, tumors, hematopoietic system disorders, neurological or psychiatric diseases, etc.

(2) Those with other organic diseases of the digestive system (such as peptic ulcer), or systemic diseases that affect gastrointestinal motility (such as hyperthyroidism, diabetes).

(3) Those who are currently using or need to continuously use medications that may affect gastrointestinal function (antidiarrheals, antidepressants, anxiolytics, gut microbiota modulators, antibiotics, etc.).

(4) Those who have taken antibiotics, steroids or other hormones, Chinese herbal preparations (including oral and intravenous administration), microecological preparations, or probiotics such as yogurt within the past 1 week.

(5) Those who have previously undergone abdominal or anorectal surgery.

(6) Pregnant or lactating women.

(7) Those with a history of allergy to related drugs or severe food allergies.

(8) Those who have participated in or are currently participating in other interventional clinical research projects within the past 3 months.

(9) Patients who refuse to be enrolled for observation or have other unstable factors, such as failure to take medication as prescribed, use of other drugs that affect efficacy assessment, making it impossible to evaluate efficacy, or incomplete data.

3. Discontinuation Criteria

(1) The patient experiences severe changes in condition or complications during the trial.

(2) The patient experiences serious adverse events during the trial, making it inappropriate to continue the clinical trial.

IV. Risks and Discomforts

All of your information will be kept confidential. The risks that participation in this study may pose to you are as follows: Your blood sample collection will be conducted strictly in compliance with aseptic procedures. The collection of specimens may involve some very minimal risks, including temporary pain, local bruising, and a small number of people may experience mild dizziness. The questionnaires may cause temporary emotional or psychological discomfort. Because you need to receive drug treatment, there is a possibility of drug-related adverse reactions. However, the drugs in the treatment regimen you are receiving are currently used routinely in clinical practice, and after years of clinical validation, their safety is very high with an extremely low incidence of adverse reactions. The most common adverse reactions are gastrointestinal reactions and skin rash, and these adverse reactions usually resolve quickly on their own after discontinuation of the medication. If you experience a serious adverse reaction during the course of treatment, we will take active treatment measures, but you will be responsible for the treatment costs yourself.

V. Benefits

You will receive quality medical care during the study. Through this study, you will gain more medical knowledge related to your disease and guidance on daily life and self-care. Testing of your specimens will assist in diagnosing the disease, provide necessary recommendations for your treatment, and offer valuable information for disease research. The results obtained from this study may be used to guide physicians' clinical practice and may benefit a broad population of patients with irritable bowel syndrome with diarrhoea.

VI. Financial Issues

The medications involved in this study, as well as the routine blood tests, blood biochemistry, routine urine tests, routine stool tests, serum biomarker tests, and electrocardiogram examinations, will be provided to you free of charge. Upon completion of the follow-up period, you will receive a subsidy of 200 RMB.

VII. Responsibilities

As a subject, you have the following responsibilities: provide truthful information about your medical history and current physical condition; inform the study doctor of any discomfort you experience during this study; do not take the following medications that may affect efficacy evaluation or interfere with the control of diarrhoea-predominant irritable bowel syndrome symptoms: ① Other Chinese patent medicines or decoctions for treating irritable bowel syndrome: such as Bupi Yichang Wan (Spleen-Invigorating Intestine-Benefiting Pills), Shenling Baizhu San (Ginseng-Poria-Atractylodes Powder), Tongxie Yaofang (Pain and Diarrhea Formula), etc.; ② Other Western medications: including other antispasmodics (e.g., pinaverium bromide), antidiarrheals (e.g., montmorillonite powder), 5-HT₃ receptor antagonists (e.g., alosetron), gut microbiota modulators (e.g., probiotics, Bifidobacterium quadruple viable tablets, Bifidobacterium triple viable capsules, etc.), antibiotics (e.g., rifaximin), and antidepressants/anxiolytics, regardless of whether they are used to treat diarrhoea-predominant irritable bowel syndrome; and inform the study doctor whether you have recently participated in other studies or are currently participating

in other studies.

VIII. Privacy

If you decide to take part in this study, your participation in the trial and your personal data during the trial will be kept confidential. Your blood, urine, stool, and pathological specimens will be identified by a study identification number rather than your name. Information that could identify you will not be disclosed to anyone outside the research team unless we obtain your permission. All members of the research team and the study sponsor are required to keep your identity confidential. Your records will be kept in a locked filing cabinet, accessible only to research personnel. To ensure that the study is conducted in accordance with regulations, if necessary, authorized representatives of government regulatory authorities or the ethics committee may inspect your personal data at the research institution in accordance with regulations. When the results of this study are published, no personal information about you will be disclosed.

Apart from this study, your medical records, blood, urine, stool, and pathological specimens may possibly be reused in other studies in the future. You may also now state your refusal to allow your medical records and pathological specimens to be used for research other than this study.

VII. Rights

You may choose not to participate in this study, or notify the researcher at any time that you wish to withdraw from the study. In such cases, your data will not be included in the study results, and your medical treatment and rights will not be affected in any way.

If you require other treatment, fail to comply with the study plan, experience a research-related injury, or for any other reason, the study physician may terminate your continued participation in this study.

You may learn about information and research progress related to this study at any time. If you have questions regarding this study, please contact the principal investigator at: _____, Tel: _____. Alternatively, if you experience any discomfort or injury during the study, or have questions concerning the rights and interests of study participants, you may contact the hospital Ethics Committee at any time, Tel: 025-52271064.