

**Mechanistic Study of Zuogui Jiangtang Shuluo Formula in  
Regulating Lipid Metabolism and Inhibiting Ferroptosis for  
the Prevention and Treatment of Diabetic Peripheral  
Neuropathy**

**Informed Consent**

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**Title Code:** HN-LL-YJSLW-2026-06

**Research Unit:** The First Affiliated Hospital of Hunan university  
of Traditional Chinese Medicine

**Department:** Endocrinology

## **Informed Consent - Informed Communication Page**

### **Dear Participant**

You are invited to participate in a scientific research study. The Principal Investigators are Professor Yu Rong and Tao Wang, from the Department of Endocrinology. The study is funded by the National Natural Science Foundation of China. Before you decide whether to participate in this study, please read the following information as carefully as possible. It will help you understand the study and why it is being conducted, the procedures and duration of the study, and the potential benefits, risks, and discomforts associated with participation. If you wish, you may discuss this with your family members or friends, or ask your physician for clarification to help you make your decision.

### **1. Introduction**

You are being invited to participate in this study because you are either a healthy individual or a patient with type 2 diabetic peripheral neuropathy. Approximately 100 participants are expected to be enrolled in this study.

### **2. Do I have to participate in this study?**

You may decide for yourself whether to participate in this study. You are entirely free to decline participation, and this will not affect your routine medical care in any way. If you choose to participate in this study, you may withdraw at any time.

### **3. Why is this study being conducted?**

The objective of this study is as follows: The pathogenesis of diabetic peripheral neuropathy (DPN) has not yet been fully elucidated, and therapeutic options remain limited. Zuogui Jiangtang Shuluo Formula is an effective prescription for the clinical treatment of DPN, but lacks evidence-based medical evidence. Therefore, this study aims to evaluate the clinical efficacy and safety of Zuogui Jiangtang Shuluo Formula in the treatment of DPN, thereby providing high-quality evidence-based medical evidence for future clinical promotion and application as well as for the development of relevant

domestic and international guidelines. Additionally, this study will further explore the pathogenesis of DPN and the mechanism of action of traditional Chinese medicine, providing a basis for clinical treatment.

#### **4. How will the study be conducted?**

Patients with type 2 diabetes and diabetic peripheral neuropathy will be recruited from the inpatient and outpatient departments of the Department of Endocrinology at the First Affiliated Hospital of Hunan University of Chinese Medicine. General clinical data, blood glucose, lipid profiles, and plasma lipidomics analyses will be collected from healthy individuals. Patients with DPN will be randomized using a randomization table into either the Zuogui Jiangtang Shuluo Formula treatment group or the positive drug control group. Clinical indicators including fasting blood glucose, glycated hemoglobin (HbA1c), four-item lipid panel, Traditional Chinese Medicine (TCM) syndrome scores, Toronto Clinical Neuropathy Score, painful DSPN and visual analog scale scores, nerve conduction velocity, and ankle-brachial index will be collected at baseline (Week 0) and post-treatment (Week 4). Plasma metabolomics and lipidomics analyses will also be performed.

#### **5. How long will my participation in the study last?**

Your participation in the study will last approximately 1 month.

#### **6. Can I stop participating in the study?**

You may withdraw from the study at any time. Please inform the researchers if you decide to do so. The researchers may terminate your participation in the study at any time for any reason, and will inform you accordingly.

#### **7. What risks might I encounter during the study?**

A potential risk is breach of confidentiality. We will fulfill our obligation to safeguard your research records. Additionally, the study process may require some of your valuable time, and we appreciate your support for our work.

#### **8. What are the potential benefits for me?**

This study will provide a relatively objective assessment of your current condition, serving as a basis for clinical treatment. We will also provide free consultation services regarding type 2 diabetic peripheral neuropathy. Your participation will contribute valuable support to the advancement of prevention and treatment for diabetic peripheral neuropathy.

**9. Will I need to pay to participate in this study?**

You will not bear any additional costs for participating in this study. The treatment you receive in the controlled study is part of routine clinical care, which you would require even if you were not participating in this study.

**10. Will I receive compensation for participating in this study?**

If you reside outside the local area or are assigned to the positive drug control group, you will receive a transportation subsidy of 200 RMB upon completion of the 1-month study.

**11. Whom should I contact if I have questions?**

If you have any questions related to this study, please contact the Principal Investigator directly. If you have any questions regarding your rights as a participant, or any complaints or suggestions, please contact the Ethics Committee Office.

**12. What medical information will be collected?**

We need your permission to collect certain medical information about you; without it, you will not be able to participate in the study. As described below, this information will be obtained from our questions, forms you complete, or your medical records. We will only collect information necessary for the study.

**13. Who will have access to your medical information?**

Only clinical research personnel at this hospital, members of the Ethics Committee, and relevant staff who oversee whether research activities comply with the hospital's regulations will be permitted to access your medical information.

We will record your medical information at this hospital, including laboratory test results, examination findings, and research questionnaire results. Therefore, this information may be reviewed by authorized personnel for the purpose of your treatment. It may also be reviewed by individuals for whom you have provided written consent, or by individuals authorized by law.

We will not use this information for any other research without your permission or that of the Ethics Committee. Once your identifiable information has been removed, the data may be used for other purposes without further consultation with you. The results of the study will be published (in public presentations or written publications), but no information that could identify you will be disclosed.

**14. What are the risks of sharing medical information?**

One of the risks of participating in this study is that more people may have access to your medical information. The research team will make every effort to protect your information, but there is a possibility that unauthorized individuals may gain access to it. This could cause you distress or affect your ability to obtain medical insurance. You may discuss with the Principal Investigator whether you are at such risk.

**15. How long will you retain my medical information?**

We will retain this information for 3 years (or indefinitely) for future reference.

**16. Can I withdraw my previous consent to share medical information?**

If you change your mind and no longer wish us to collect or share your information, please contact the Principal Investigator. We will then terminate your participation in the study, but we may continue to use the information already collected about you.

## **Informed Consent Form · Consent and Signature Page**

**Clinical Research Project Title:** Study on the Mechanism of Zuogui Jiangtang Shuluo Formula in Regulating Lipid Metabolism to Inhibit Schwann Cell Ferroptosis for the Prevention and Treatment of Diabetic Peripheral Neuropathy

**Ethics Review Approval Number:** Ethics Review Approval Number: Ethics Committee of the First Affiliated Hospital of Hunan University of Chinese Medicine (HN-LL-YJSLW-2026-06)

### **Statement of Consent**

I have read the above information about this study and have had the opportunity to discuss the study with the physician and to ask questions. All of my questions have been answered to my satisfaction.

I understand the potential risks and benefits associated with participation in this study. I acknowledge that participation is voluntary, that I have had sufficient time to consider this decision, and that:

I may consult the physician for additional information at any time.

I may withdraw from this study at any time without facing discrimination or retaliation, and my medical treatment and rights will not be affected.

I also understand that if I withdraw from the study prematurely, particularly if withdrawal is due to medication-related reasons, it would be beneficial for both myself and the overall study if I report any changes in my condition to the physician and complete the corresponding physical examinations and laboratory tests.

If I need to take any additional medications due to changes in my condition, I will consult the physician in advance or inform the physician truthfully afterwards.

I consent to the Ethics Committee or researchers accessing my study data.

I consent ☐ or decline ☐ to the use of my medical records and pathological examination specimens by other studies beyond this research.

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

Finally, I have decided to consent to participate in this study.

Participant Signature: \_\_\_\_\_ Date: \_\_\_\_ Year \_\_\_\_ Month \_\_\_\_ Day

Participant Contact Number: \_\_\_\_\_ Mobile Phone: \_\_\_\_\_

I confirm that I have explained to the participant the details of this study, including their rights and the potential benefits and risks, and have provided them with a signed copy of the informed consent form.

Doctor's signature: \_\_\_\_\_ Date: \_\_\_\_ Year \_\_\_\_ Month \_\_\_\_ Day

Day Doctor's working number: \_\_\_\_\_ Mobile phone : \_\_\_\_\_

Contact numbers of the Ethics Committee Office of the First Affiliated Hospital of Hunan University of Traditional Chinese Medicine and the department where subjects complained: 0731-85600565.