Informed consent for a clinical study performed by First Affiliated Hospital of Guangdong Pharmaceutical University

(Version 1, November, 11, 2017)

Dear Patient:

You are invited to participate in a clinical study to evaluate the therapeutic effects of Compound Zhenzhu Tiaozhi capsules on nonalcoholic fatty liver disease, conducted by First Affiliated Hospital of Guangdong Pharmaceutical University. The study has been approved by the ethics committee of our university. Please read the following information carefully before deciding to participate in this study, and feel free to ask questions if there is anything unclear or if you would like more information. Our doctors will answer all your questions.

1. Objectives

To evaluate the relationship among the function of the intestinal mucosal barrier, SIBO, and NAFLD; to assess the therapeutic effects of Compound Zhenzhu Tiaozhi capsules, metformin, and simvastatin on NAFLD; to analyze the relationship of Compound Zhenzhu Tiaozhi capsules, metformin, and simvastatin in improving NAFLD and related parameters with the function of intestinal mucous barrier and SIBO.

2. Methods

You have been diagnosed with nonalcoholic fatty liver disease. After recruitment, you will be assigned randomly into the metformin group, simvastatin group, Compound Zhenzhu Tiaozhi capsules group, or TLC group. All drugs applied in the study are already used in clinical practice. Whatever group you participate in will not affect your treatment. To participate in the study you will need to cooperate with the doctors to complete the following observational work:

2.1. Please tell the doctors your detailed medical history, and perform all the related tests, which can help the doctors make an accurate diagnosis and decide whether you are suitable to participate in this study.

2.2. During the treatment, you will need to report your physical conditions honestly to doctors, so that they can make records and decide the next stage of treatment considering your overall condition.

3. Potential Side Effects

3.1. Metformin: diarrhea, nausea, vomiting, bloating, asthenia and other abdominal discomforts; other rare side effects include: stool abnormalities, hypoglycemia, excessive sweating, weight loss; metformin can cause reduced vitamin B12 absorption, but it is rarely enough to cause anemia.

3.2. Simvastatin: This drug is generally well tolerated. Most of the side effects are only mild and transient. In a clinical study, less than 2% of patients needed to withdrawal due to the adverse reactions. The adverse reactions include abdominal pain, constipation, and abdominal bloating; rare side effects include fatigue, asthenia, and headache; very rare side effects include myopathy and elevated serum transaminase.

3.3. Compound Zhenzhu Tiaozhi capsules: Compound Zhenzhu Tiaozhi capsules (Register Number: 20120220) consists of 8 Chinese herbal medications, such as glossy privet fruit, goldthread, bergarmot, and panax notoginseng. It has a good efficacy for metabolic syndrome, especially for non-alcoholic fatty liver disease. Allergies to this drug rarely occur.

The above-mentioned side effects are mild, which can disappear after drug withdrawal. There are no reports on serious adverse reactions. The doctors will closely observe your condition to ensure that you are in a safe state. You will be informed honestly about any changes and news related to the medications during the study.

4. Benefits

Based on the established protocol, you will receive treatment and undergo physical examinations. We will closely observe and check your tests regularly. Before recruitment, we need to perform comprehensive physical examinations. Only if your condition and tests meet our inclusion criteria, will you be enrolled in the study. During treatment, your health will be supervised by a well-established medical team and they will monitor your health. At the same time, you will have privileged access to convenient services at the follow-up visits if you need. Moreover, you will be offered free FibroTouch detection three times in the first, third, and sixth months after you have completed this project. The FibroTouch is the core detection of this study. Our researchers will observe your condition, check your test results carefully, and make records.

5. Participation and Withdrawal

Your participation or withdrawal in this study are entirely voluntary. Refusal to participate in this study will not affect your relationship with doctors and alternative medical treatments, and will involve no prejudice in future or loss of benefits.

6. Enquiries

If you have any questions about this study, including the rights of participants or questions about the drugs, please feel free to directly contact the doctors who are responsible for the study at any time. The doctors will answer all your questions honestly.

7. Confidentiality of records

During the whole trial, you will be covered by the rights dictated by the research institute for the protection of the confidentiality of your personal identity and personal data. Clinical institutes that apply for and undertake this trial will have access to all your records and results of this study. Some data will be published and used only for research purposes.

I have read or been informed of the content in this consent form before I decide to participate in this study. I have been given sufficient time to consider this decision and all enquires of this study have been explained clearly to me. I have been given the right to make further enquiries. I also understand that I can withdraw my consent and discontinue from the study at any time. I voluntarily consent to participate in this study and cooperate with the researchers.

Patient's signature

Date (date month year)