Study on the clinical efficacy and effect mechanism of auricular acupoint stimulation on functional dyspepsia with sleep disorders

Informed Consent Form · Informed Notification Page

Version Number: v1.0 Version Date: 2024-03-10

Dear patient,

You are currently attending the clinic of Zhejiang TCM Gastroenterology.

We will invite you to participate in an observational study of the clinical efficacy and effect mechanisms of ear acupoint stimulation on functional dyspepsia with sleep disorders to clarify the clinical efficacy of ear acupoint stimulation on functional dyspepsia with sleep disorders.

Before you decide whether to participate in the study, read the following as carefully as possible. It will help you understand the study and why the study was conducted, the procedures and duration of the study, the benefits, risks and discomfort you may have after participating in the study. If you wish, you can also discuss it with your relatives and friends, or ask your doctor to give an explanation to help you make a decision.

Research introduction

I. Research background and research objectives

Functional dyspepsia (Functional Dyspepsia, FD) refers to a chronic digestive system disease with upper abdominal symptoms originating in the gastroduodenal area. After clinical examination, including upper gastrointestinal endoscopy, excluding organic diseases causing the above symptoms. According to the Rome IV criteria, functional dyspepsia is divided into two categories: postprandial discomfort syndrome (Postprandial Distress Syndrome, PDS) and epigastric pain syndrome (Epigastric Pain Syndrome, EPS). FD not only seriously affects the quality of life of patients, but also causes a heavy socioeconomic burden. Therefore, the active prevention and treatment of FD, especially P D S, has become an unavoidable problem in clinical practice.

Epidemiological surveys show that about 30% of FD patients have sleep disorders, anxiety and depression, and many anti-negative mood drugs themselves cause gastrointestinal related side effects, which are considered to be the key causes of recurrent symptoms. In recent years, the brain-gut axis has been increasingly valued. The microbe-gut-brain axis can also affect brain function through the release of neurotransmitters and inflammatory mediators. Furthermore, interactions between bile acids and the gut microbiota may also affect the normal function of the gut. However, the relationship between specific bile acids, the microbiota, and functional dyspepsia remains uncertain.

Currently, effective and safe treatments for FD with sleep disorders are still very limited. Recently, the method has significant advantages in the treatment of FD with sleep disorders. This study is planned to study the clinical efficacy and effect mechanism of auricular acupoint stimulation on functional dyspepsia with sleep disorders. To provide clinicians with more treatment means and ideas, promote and apply green diagnosis and treatment methods, bring good news to more patients, and produce significant economic and social benefits.

The ethics committee has considered that the study complies with the principles of the Declaration of Helsinki.

Two, who should not participate in the study

A . Secondary insomnia caused by drugs or other diseases;

B . Combined with other mental diseases, combined with serious diseases of the heart, liver, kidney and other systems;

C . Those who have received this treatment or participated in other clinical trials in the past half year;

D . There are contraindications to ear sticking, such as allergy to skin preparation, damage to the contact area of ear patch; E.

Pregnant and lactating women.

3. What will you need to do if you participate in the study

1. Before you are enrolled in the study, your doctor will ask and record your medical history to determine whether you can participate in the study.

2. If you have completed the above inspection, you will follow the following steps:

You were randomly assigned to the test group or the control group, treated with Mosalbil citrate spread tablets, BID, 1 tablet (5mg) at a time, and warm water 30 minutes before the meal.

Control group treatment: you attach the ear hole with the seed to the earlobe. For ear pressing treatment, the strength of the state of gas (acid, numbness, heavy, distension, etc.). Frequency: 3 times a day, within half an hour after the meal, the pressing time is about 1 ~ 2 minutes, the number of presses is about 30 times, and both earlobes are pressed at the same time. Treatment duration was 2 weeks, 1 day apart, for a total of 7 days. Go to the hospital once a week to replace the ear acupoint patch.

Test group treatment: you will stick the ear point with no seed to the eararmor area. The ear acupoint pressing method is the same as above, and the pressing strength is subject to the qi state (acid, hemp, heavy, swelling, etc.). Frequency: 3 times a day, within half an hour after the meal, the pressing time is about 1 ~ 2 minutes, the pressing times are about 30 times, and the bilateral earpiece is pressed at the same time. Treatment duration was 2 weeks, 1 day apart, for a total of 7 days. Go to the hospital once a week to replace the ear acupoint patch.

All of the above operations are guided by professional nurses in the acupuncture department.

The observation will last 2 weeks and follow up to 8 weeks. We will collect your relevant information, including:

① Baseline data: gender, age, height, weight, blood pressure, year of education, etc. Patient diagnosis, past medical history and concomitant medication at enrollment.

② efficacy indicators

(1) Main outcome measures:

Treatment-response rate for 2 weeks.

(2) Secondary outcome measures:

.8Treatment response rate at week A

B . Assessment of clinical functional dyspepsia scales before treatment, after 2 weeks, and 8 weeks after treatment: 10 nipin dyspepsia index

Number (SF-NDI);

C . Assessment of the clinical sleep scale before treatment, 2 weeks later, and 8 weeks later: Pittsburgh Sleep Quality Index (PSQI), Self-assessed Anxiety Scale (SDS), Self-assessed Depression Scale (SAS);

D . Objective sleep quality monitoring: The kinograph collects data including sleep efficiency, total sleep time, awakening time after sleep, sleep fragmentation index, etc.

E . Assessment of autonomic function before, 2 weeks, and 8 weeks: hyperarousal scale; heart rate variability; F. Tongue and vein imaging monitoring before treatment, 2 weeks after treatment, and 8 weeks later.

(3) Safety indicators: adverse events.

If you need to take stool and serum samples, you also need to observe the following indicators, if not, please ignore.

③ Efficacy mechanism study:

(1) Metabolomics study: serum samples from days 0,2 weeks and 8 weeks were kept for metabolomics study;

(2) Intestinal microecology study: fecal samples from day 0,2 weeks and 8 weeks were retained for intestinal microecology study.

3. Other matters requiring your cooperation

You need to follow up at the time agreed upon by your doctor and you. Your follow-up is important because the doctor will determine if the study measures you receive really work.

If you need any other treatment, please contact your doctor in advance.

4. possible benefits of participating in the study

In order to compensate for the inconvenience caused by participating in this study, you will get the comprehensive evaluation report of sleep quality of the new bracelet 3 times and 3 times of the tongue pulse imaging instrument.

If you take stool and serum samples, you will also get three tests of functional dyspepsia with sleep disorders and intestinal microecology.

Also you and society will may benefit from this study. Such benefits include the potential for improvement in your condition and the possibility that this study may help develop a new treatment for other patients with similar conditions.

5. possible adverse reactions, risks, discomfort and inconvenience in the study

Although no adverse effects of the study method have been found so far, if you experience any discomfort, or new changes in the study, or any unexpected circumstances, please inform your doctor and he / she will make a judgment and medical treatment.

If an adverse event occurs in the clinical study, the investigator will determine if it is related to the study. If it is related to the study, the investigator / research group will provide the cost and corresponding financial compensation for the damage related to the study.

In addition, research interventions may be ineffective and may continue to develop due to ineffective treatment or other diseases. During the study period, if the study intervention fails, the study will discontinue and switch to other treatments that may be effective.

Is personal information confidential?

Your medical records (study medical records / CRFs, laboratory test sheets, etc.) will be kept intact in the hospital, and your doctor will record the laboratory test results on your outpatient medical records. The investigator or research group representative member, the ethics committee will be allowed access to your medical records. No public report on the results of this study will disclose your personal identity. We will be permitted by law
Inside, do everything possible to protect the privacy of your personal medical data.

Besides this study, it is possible that your medical records and examination specimens will be used again in future studies. You may also now declare denying other studies than this study to utilize your medical records and specimens.

7. How do you get more information?

You can ask any questions about this study at any time. Your doctor will leave you his / her phone number so you can answer your questions.

If you have any complaints about participating in the study, please contact the hospital ethics committee office.

Your doctor will promptly notify you if there is any important new information during the study that may affect your willingness to continue participating in the study.

8. You can voluntarily choose to participate in the study and withdraw from the study

Participation in the study depends entirely on your willingness. You may refuse to participate in the study or withdraw from the study at any time during the study, which will not affect your relationship with your doctor or the loss of your medical treatment or other benefits.

Your doctor or investigator may suspend your participation in this study at any time for your best interest.

You may not participate in this study, or you may opt out of the study. If you withdraw from the study for any reason, you may be asked about your use of the treatment method. You may also be required to have a laboratory examination and a physical examination if your doctor thinks it is necessary. This is very good for protecting your health.

9. What should I do now?

You will decide whether to participate in this study. You can discuss it with your family or friends before making a decision.

Before you make your decision to participate in the study, please ask your doctor any questions until you fully understand the study.

Thank you for reading the above materials.

If you decide to participate in this study, please tell your doctor or research assistant that he / she will arrange everything for you about the study.

Please keep this information.

Informed Consent Form · Consent signature page

Clinical Research Project Name: Clinical efficacy and effect mechanism of auricular stimulation on functional dyspepsia with sleep disorders
EC Approval No.: Upper right corner of EC Approval

Consent statement

I have read the above introduction to this study and have the opportunity to discuss and ask questions about this study. All the questions I have raised have been answered satisfactorily.

I am aware of the risks and benefits that may arise from participating in this study. I know that the study is voluntary, I confirm I have enough time to consider this and understand:

I I can ask the doctor for more information.

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

I am also aware that if I withdraw from the study, especially from the study due to the treatment method, I should tell the doctor about the changes in the condition and complete the corresponding physical examination and physical and chemical examination, which will be very beneficial to me and the whole study.

If I need to take any other related treatment due to the change in my condition, I will ask the doctor's advice in advance or tell the doctor truthfully afterwards.

I agree with the ethics committee or the sponsor representative and the study quality supervisor.

I agree with □ or reject □ for studies other than this study utilizing my medical records and examining specimens.

I will obtain a copy of the signed and dated informed consent form.
Finally, I decided to consent to participate in this study.

Subjects signed:_____year_____moon_____ sun

Subject Contact Number:_____cell-phone number:_____

Signature of the legal agent (if any):_____date:_____ year___moon___sun

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I confirm that the patient has explained the details of the study, including its rights and possible benefits and risks, and gave him a copy of the signed informed consent form.

Investigator's signature:_____date:_____year_____ moon_____sun

Investigator work Telephone:_____cell-phone number:_____

Ethics Committee Office of the First Affiliated Hospital of Zhejiang Traditional Chinese Medicine University

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