The Effectiveness and Mechanism Study of Auricular Needling in Treating Cancer Induced Anorexia Informed Consent Form

Informed notification page

Dear patient: Hello!

You are welcome to voluntarily participate in the research on the effect and mechanism of the intervention on appetite in patients with advanced clinical tumors, and express my heartfelt thanks for your participation grateful. Before deciding whether to participate, it is necessary for you to understand the purpose of this trial, the investigational drug, the risks that may be brought to you. Expect what you do and your rights as a subject. Please read this subject instruction carefully. You can also share and discuss with your relatives, friends to help you make a decision.

1. Research background

Cancerous anorexia is a common clinical symptom in cancer patients. Among advanced patients, anorexia is as high as 80%, of which gastric cancer patients account for about 60%.Once related anorexia occurs in tumor patients, it not only affects the implementation of the treatment plan, but also increases the difficulty of treatment and affects the patient's health,quality of life, and can lead to the direct death of patients with malignant tumors due to malnutrition and exhaustion, affecting the survival time of patients and becoming the immediate cause of death of the patient. How to optimize the selection of interventions for the prevention and treatment of cancerous anorexia, and explore its mechanism of action, is also our traditional Chinese medicine tumor the scientific problems faced by doctors that need to be solved in clinical practice.

At present, the treatment of cancer anorexia includes drug therapy, nutritional therapy and psychological therapy, etc. The curative effect is different, and there are some problems can not be ignored. Traditional Chinese medicine has certain research results in the treatment of improving appetite. By combining the study of ancient documents with modern research, Our department takes a new approach and proposes a new clinical treatment idea, which involves auricular acupuncture in the treatment of cancerous anorexia. In pre-clinical trials, The initial effect is satisfactory, ear acupuncture treatment can significantly improve the patient's appetite, showing its simple, convenient, inexpensive and proven characteristics, safe and reliable, However, this technology still needs to be further verified, standardized and perfected. Auricular acupuncture, which is highly accepted in the West, lacks high-quality clinical efficacy. Evidence-based evidence and mechanism research have influenced the influence of auricular acupuncture treatment, and it is worthy of our in-depth clinical research.

2. Research introduction

This research has been funded by the National Natural Science Foundation of China and is a general project of the National Natural Science Foundation of China (Project No. 81573958), and has been approved by the Ethics Committee of Xiyuan Hospital, Chinese Academy of Chinese Medical Sciences.

The purpose of this study is to objectively evaluate the clinical efficacy of auricular acupuncture in improving appetite in cancer patients, to verify and improve its technology, and to determine the treatment of acupoints and the course of treatment provide a strong evidence-based medical basis for auricular acupuncture interventional tumor treatment.

A total of 60 subjects participated in this study, all of which were conducted in the outpatient or inpatient department of Xiyuan Hospital, Chinese Academy of Chinese Medical Sciences. This study adopts a randomized, parallel-controlled study method was used. Based on the principle of voluntary participation, according to the ratio of 1:1, it is planned to include 60 subjects who meet the inclusion criteria randomly divided into ear acupuncture group and control group, 30 cases in each group. The therapeutic interventions in both groups are not going to be or are going to be related to your tumor.

Standard treatments such as chemotherapy and radiotherapy have interventions, but according to the grouping, the subjects in the ear acupuncture group will be treated on the basis of conventional treatment. You need to receive 4 weeks of ear acupuncture treatment, and observe and faithfully record your treatment process and changes in TCM syndromes before and after treatment.

A series of scales such as symptom-based anorexia assessment, simplified appetite scale, and routine follow-up data were collected and organized. Routine safety testing of your blood samples may be required to assess the safety of the treatment.

3. Who is suitable for participating in the study?

Age 18-80 years old, no gender restrictions; Malignant tumors diagnosed by pathology/cytology, stage III or IV; meet the diagnostic criteria for tumor anorexia; KPS score ÿ 60 points; voluntarily accept the treatment in this trial and participate in this research voluntarily; the investigators judge appropriate eligible to enroll.

4. Who should not participate in the research

Those with the following conditions are not suitable to participate in this clinical study. Those who do not meet the inclusion criteria; blood routine, liver and kidney function indexes are abnormally exceeded more than 2 times; those with obvious eating disorders, gastrointestinal obstruction symptoms, heart disease and poor control of diabetes; those who are receiving progesterone, corticosteroids hormone therapy such as hormone therapy; participate in other clinical investigators; pregnant women, lactating women, and mentally ill patients.

5. Overall process

Before being selected into the study, the physician will explain the nature, purpose and content of the study you are conducting the study, and decide according to your wishes whether to join this study.

After you decide to participate in this study, your doctor in charge will review your medical history and register your basic information, which will take you nearly 1 month physical and chemical tests such as blood routine, stool routine, urine routine, liver and kidney function, chest X-ray or chest CT, abdominal B-ultrasound or abdominal or pelvic CT and other imaging tests, and the results of pathological genetic testing (if you have done it). and associated symptom-based assessment of anorexia, brief filling in a series of scales such as appetite scale, acupuncture expectation scale and TCM symptoms.

During the entire study, there will be no drug intervention other than the necessary

treatment for your disease. According to the principle of randomness, Choose whether to receive auricular acupuncture. Those who received auricular acupuncture were divided into the auricular acupuncture group, and those who did not receive auricular acupuncture were divided into the control group. ear acupuncture, per 2-3 times a week for 4 weeks. After joining the group, we will observe and record your treatment process, TCM syndrome types, and routine inspection items.The changes in the condition should be truthfully reported to the doctor. Relevant symptom-based anorexia required at 2 weeks, 4 weeks, and 8 weeks of enrollment fill in a series of scales such as assessment and simplified appetite scale, acupuncture expectation scale and TCM symptoms, except for routine follow-up examination items for cancer patients in addition, no special items of inspection or testing were required for this study. The study lasted 8 weeks.

Please come to the doctor according to the follow-up time agreed by your doctor and you. Your follow-up is very important, and your information is true and complete.It will have a significant impact. You'd better be able to return to the hospital for follow-up, and you need to check the copy of the information to ensure that the information is authentic. If it is inconvenient for you to return to the hospital for some reason, please accept our telephone follow-up.

All the treatments you receive are very important to us. Please follow your doctor's instructions to take medicines, and ask you to take medicines in a timely and objective manner after each medicine record. Also record any medications you must continue to take during the trial due to other medical conditions. You cannot use other than usual treatments during the study other non-scientific treatment methods such as home remedies and prescriptions. If you need other treatment, please contact your doctor in advance.

6. Your rights and interests

(1)The researcher will introduce the research process to you, and the participation or not will follow the voluntary principle. The investigator reports to you all events so that you can decide at any time whether to continue attending. If you have any questions, you can call or ask the investigator directly. you will be in access to good medical care during the study. You may refuse to participate in this study, or withdraw from the study at any time during. Neither will affect your relationship with your doctor, nor will it affect the loss of your medical care or other benefits, you can withdraw from this study at any time. Without discrimination or unfair treatment, medical treatment and rights will not be affected. You don't have to choose to treat your disease participate in this study.

(2) You and the society may benefit from this trial. Such benefits include a possible improvement in your symptoms and a possible improvement in your quality of life. You will receive good medical care during your study. At the same time, your participation may contribute to the study of the mechanism of action of ear acupuncture interventional tumor therapy contribution, this research will potentially help other patients with similar conditions.

(3) The ear acupuncture during ear acupuncture treatment is provided by the research group without any other payment.

7. Your obligations

Adhere to the principle of voluntary participation and sign the informed consent form before the start of the trial.

Follow the clinical trial protocol and follow the investigator's unified arrangement.

Cooperate with the researcher to complete the experimental task.

During the trial, please do not use other drugs that are not required by the disease. If you must use it, please contact the investigator.

8. Possible adverse reactions and safety measures

The ear acupuncture treatment used in this study has been used in the clinical treatment of various diseases for a long time, and has been recognized and accepted by the majority of patients. In the patients in the ear acupuncture group, possible adverse reactions related to the treatment include: local skin allergic reaction or pain, acupuncture dizziness, etc.

If you experience any discomfort during the study, or new changes in your condition, or any unexpected circumstances, whether drug-related or not. You should notify your doctor in a timely manner, and the competent doctor will make judgment and medical treatment. Doctors will do their best to prevent possible damage to come. If a serious adverse event occurs in a clinical study, a medical expert committee will determine whether it is related to the study protocol, If it is confirmed that it is related, the research unit of the project can provide corresponding compensation.

You will need to visit the hospital on time or receive telephone follow-up visits during the study period. These are tests that need to be done to understand your treatment effect, please cooperate.

In addition, the research may progress or the patient is not suitable to continue the research due to other reasons such as comorbidities. The study will be discontinued.

9. Reasons for terminating your participation in the trial

(1) The researcher determines that conducting this research is harmful to you.

(2) If you have serious adverse events, complications and special physiological changes, it is not suitable to continue the study

(3) Disease progression.

(4) Death due to tumor-related or non-tumor-related causes.

(5) The relevant state departments cancel this research.

In the event of the above situation, the investigator has the right to terminate your participation in the trial without your consent.

10. You may withdraw from this trial at any time

The investigator will evaluate you in a timely manner during treatment. You can withdraw from the trial at any time in the following situations, and the investigator will evaluate you: Assess your health status and disease progression, and give symptomatic treatment:

(1) When you have unbearable skin irritation or local pain;

(2) Weekly Karnofsky score decreased by more than 40 points;

(3) Lose more than 30% of body weight per week.

11. Confidentiality

All information about you, including your identity, medical history, medical condition, physical examination and laboratory test results, etc., will be kept under the law permitted, it is strictly confidential. Only authorised investigators, ethics committees and research project authorities have access to your records. The Food and Drug Administration is permitted to review your medical records related to this study to verify the authenticity of the information collected by this study and accuracy, but does not involve your personal details. Your name will not appear in any public information or reports related to this research.

12. Post

Regardless of the findings, we will do our best to publish the findings.

Thank you for reading the above information. If you decide to participate in a clinical study, tell your doctor and he/she will arrange for you of bed research.

Please keep this information.

Informed consent signature page

Trial name: Intervention effect and mechanism of ear acupuncture on appetite in patients with advanced clinical tumors:

Project undertaking unit: Xiyuan Hospital, Chinese Academy of Chinese Medical Sciences

This is a general project of the National Natural Science Foundation of China (Project No. 81573958).

Statement of Consent

I have read the above description of this study and have had the opportunity to discuss and ask questions about the study with my doctor. I propose all questions were answered satisfactorily.

I am aware of the possible risks and benefits of participating in this study. I understand that participation in the study is voluntary and I confirm that there is sufficient time for this consider it and understand that:

• I can always ask my doctor for more information.

• I can withdraw from this research at any time without discrimination or unfair treatment, and my medical treatment and rights will not be affected.

I am also aware that if I drop out of the study, especially due to medication, if I report a change in my condition.It will be very beneficial for me and the whole research to complete the corresponding physical examination and physical and chemical examination.

If I need to take any other medication due to a change in my condition, I will seek the advice of my doctor beforehand, or tell the truth after the fact to the doctor.

I will get a signed and dated copy of the informed consent form. At the same time, I allow the National Natural Science Foundation of China, the Ethics Committee Committee and relevant researchers review records.

Finally, I decided to agree to participate in this study.

Patient Signature: _____ ID number: ____

Patient contact number:____ phone number:____

Date:___Year___month___day

Signature of legal representative:_____ ID number: ____

contact number:_____ phone number: ___

Date:___Year___month___day

I confirm that the details of this trial, including its rights and possible benefits and risks, have been explained to the patient and given a signed a copy of the informed consent form.

Doctor's signature:_____ Date:__Year__month__day

Doctor's work phone number: _____ phone number:_____

Office of the Medical Ethics Committee of Xiyuan Hospital Tel: 010- 62835646

Attachment: Record of Informed Consent Process

Informed consent process record

When the subject is unable to read or sign the informed consent form, this page is recorded by their designated agent/guardian.

<table>
<tr><td rowspan="4">The method by which the subject gave informed consent</td><td colspan="5">The doctor/nurse reads the content of the informed consent form to the subjects and answers subject's question.</td></tr>
<tr><td colspan="5">The agent will read the content of the informed consent form to the subject, and the doctor will answer subject's question.</td></tr>
<tr><td colspan="5">The subject's legal representative shall read the subject's instructions and answer all questions the doctor's answer has been obtained.</td></tr>
<tr><td colspan="5">Other :</td></tr>
<tr><td>Whether the subject has understood all the subject instructions</td><td>Yes__</td><td>No___</td><td colspan="3">Not applicable:_____</td></tr>
<tr><td>Whether the subject has understood all the subject instructions</td><td>Yes__</td><td>No___</td><td colspan="3">Not applicable:_____</td></tr>
<tr><td>Whether the subject agrees to participate in this trial</td><td>Yes__</td><td>No___</td><td colspan="3">Not applicable:_____</td></tr>
<tr><td>Does the subject agree to all the terms of the statement on the "Informed Consent Page</td><td>Yes__</td><td>No___</td><td colspan="3">Not applicable:_____</td></tr>
<tr><td>Reasons why subjects were unable to sign this informed consent form</td><td>Disability</td><td>Illiteracy _____</td><td>Minor___</td><td colspan="2">Other_____</td></tr>
<tr><td>Agent-Subject Relationship</td><td>Husband and wife___</td><td>Parents _____</td><td>Children _____</td><td>Brothers ____</td><td>Other ____</td></tr>
<tr><td colspan="6">Remark:</td></tr>
</table>

Signature of the subject's agent/guardian:

Name (regular script): sign: date of signature:

Version number:2016-05-01
Effective date:2016-05-01 to 2017-12-31