Informed consent · informed consent page

Dear Mr/Miss,

We will invite you to participate in a study, this study is supported by the project of the National Natural Science Foundation of China (No. 81703898, 81603702, 81603700 and 81774108) and the commercial sponsorship of SINCH Pharmaceuticals Tech. Co., Ltd. This study protocol has been reviewed by the Chinese Registered Clinical Trial Ethics Review Committee (NO.ChiECRCT-20170084) and approved for clinical study. Before you decide whether or not to participate in this study, please read the following as carefully as possible. It will help you understand the study and why it was conducted, the procedures and duration of the study, and the benefits, risks and discomfort that may result from your participation in the study. If you wish, you can also discuss it with your relatives or friends, or ask your doctor for an explanation to help you make a decision.

I. Research background and purpose

1.1 Disease burden and treatment status

Postoperative ileus (POI) refers to the stagnation of gastrointestinal propulsion caused by surgical operation after abdominal surgery, which is mainly manifested as abdominal pain, abdominal distension, nausea and vomiting, cessation of exhaust and defecation, and intolerance of solid food.

Postoperative intestinal paralysis is usually temporary, but if the duration of intestinal paralysis is prolonged, it may lead to serious complications such as surgical incision dehiscence, intestinal anastomotic fistula, abdominal infection, intestinal ischemia, and aspiration pneumonia.

A retrospective cohort study of nearly 500 U.S. hospitals showed that postoperative ileus was an important cause of longer hospital stays and higher medical costs for patients undergoing abdominal surgery. The United States spends more than $1.46 billion annually on treatment for POI. At present, measures used in treating POI mainly include: perioperative rational use of narcotic drugs and opioids, eat early after surgery, avoid to use nasogastric tube after operation, early ambulation, postoperative epidural analgesia, restrict fluid intake, the minimally invasive surgery (such as laparoscopic), drug therapy, chewing gum, etc. However, although there are many treatment measures, they are affected by many factors (such as complicated operation, whether the patient accepts, cost-benefit ratio, surgical conditions, etc.), and the mechanism of POI is complex and far from clear, so the clinical treatment effect is still not ideal.

POI is still a clinical problem that seriously affects patients' postoperative recovery.

Therefore, it is necessary to find more effective, convenient and economical treatment methods.

1.2 purpose of this study

The purpose of this study is to assess the effect of TEAS on clinical recovery of bowel function after laparoscopic colon surgery and explore the mechanism of TEAS treatment on POI.

II. What will be required to participate in the study?

1.Before you are enrolled in the study, the doctor will inquire and record your medical history, and perform physical examination, blood routine, urine routine, stool routine, liver function, kidney function and other physical and chemical examinations, as well as 12-lead electrocardiogram.

You are eligible for inclusion. You may participate in the study voluntarily and sign the informed consent.
If you do not wish to participate in the study, we will treat you as you wish.

2. If you are willing to participate in the study, you will follow the following steps:

- **Sign the informed consent**

- **TEAS treatment**

We will provide you with TEAS treatment in 3 consecutive days before surgery, twice a day, each time for 30 minutes, giving another acupoint electrical stimulation treatment for 30 minutes before anesthesia.

- **Clinical test indicators:**

You will need to cooperate to provide the following information, which will be recorded by the researcher

- First defecation time (h) i.e., time to first anal defecation after laparoscopic surgery.
- Time to first flatus (h), time to tolerance of solid oral diet (h), GI-2 (composite outcome of time to first defecation and time to tolerance of oral diet), time to walk independently (h)
- Pain will be assessed using the visual analogue scale (VAS) on postoperative days 1, 2 and 3 (scale of 0 to 10, where 0 represents complete absence of pain and 10 represent the worst pain intensity).
- Inflammatory mediators (IFN-β, IFN-γ, IL-6 and IL-1β) in blood will be measured before TEAS/STEAS intervention and on days 1, 3 and 5 after the

operation.

- Postoperative complications will be recorded, and the follow-up period will be at least 6 months.

3. Clinical safety evaluation:

Patients were assessed for clinical safety by spontaneous reporting, direct observation by clinicians, or by non-inductive questioning about adverse events.

- **Quality control during operation and anesthesia:**

All surgery will be carried out under general anesthesia, using standardized anesthetic procedures. After surgery, all patients will remain in the post anesthesia care unit and then return to the ward for recovery until discharge. The perioperative management of all patients will be standardized.

- **Postoperative complications will be recorded, and the follow-up period will be at least 6 months.**

Other matters requiring your cooperation
You must come to the hospital according to the follow-up time agreed by the doctor and you (generally medical records, personal treatment diary card, etc.).
Your follow-up is important because your doctor will determine whether the treatment you receive is truly effective and will guide you in a timely manner.

III. Potential benefits of participating in the study

Although there is evidence that transcutaneous electrical acupoint stimulation has a satisfactory effect, it is not guaranteed to be effective for you.
The percutaneous electrical stimulation of acupoints used in this study is not the only method for the treatment of postoperative intestinal paralysis.
If it does not work for you, ask your doctor about alternative treatments that may be available.

IV. Possible adverse reactions, risks, discomfort and inconvenience

The transcutaneous electrical acupoint stimulation used in this study has the advantages of safety, noninvasiveness and small impact on cardiovascular system. No serious adverse reactions have occurred during the treatment.
If you experience any discomfort, illness aggravating or any unexpected circumstances during the study, whether related to the study or not, you should inform your doctor in time. He/she will make a judgment on this and give appropriate medical treatment.
During the study, you need to come to the hospital on time for follow-up visits and

some examinations, which may take up some of your time and may also cause trouble or inconvenience to you.

V. Related expenses

The drugs and related tests used in this study are free of charge. If you have any injury related to this study, the research group will pay your medical expenses. In case of serious adverse events, the research team will pay compensation according to relevant national regulations. For other diseases that you combine at the same time, the treatment and examination required will not be free of charge

VI. Confidentiality of personal information

Your medical records (study records /CRF, lab notes, etc.) will be kept intact in the hospital you visit.
Your doctor will record the results of tests and other tests on your medical record.
Researchers, ethics committees and drug regulators will be allowed to access your medical records.
Any public report on the results of this study will not disclose your personal identity.
We will make every effort to protect the privacy of your personal medical data to the extent permitted by law.
In accordance with medical research ethics, in addition to personal privacy information, test data will be available for public inquiry and sharing, which will be limited to web-based electronic databases, ensuring that no personal privacy information will be disclosed.

VII. How to get more information?

You may raise any questions about this study at any time and get the corresponding answers.
If there is any important new information during the study that may affect your willingness to continue to participate in the study, your doctor will inform you in time.

VIII. You may voluntarily participate in the study or withdraw from the study

Participation in the study is entirely up to you.
You may refuse to participate in the study or withdraw from the study at any time during the study, which will not affect the relationship between you and the doctor, nor will it affect your medical treatment or the loss of other benefits.
In your best interests, the doctor or researcher may discontinue your participation in this study at any time during the study.
If you withdraw from the study for any reason, you may be asked about the use of the test drug.
You may also be required to have a laboratory and physical examination if your

doctor deems it necessary.

IX. What should I do now?

Participation in this study is up to you (and your family).
Before you make a decision to participate in the study, please ask your doctor as many questions as possible. Thank you for reading the material. If you decide to participate in this study, please tell your doctor that he/she will arrange all matters related to the study for you. Please keep this information.

Informed consent

Clinical study title: Pretreatment with transcutaneous electrical acupoint stimulation to prevent postoperative ileus in patients undergoing laparoscopic colon surgery: study protocol for a randomized controlled trial
Project unit: Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine
Project partner: _ _ _ _ _ _ _ _ _ _ _ _ _
Project assignment no.: _ _ _ _ _ _ _ _ _ _ _ _ _
Agree with the statement
I have read the above introduction to this study and have the opportunity to discuss and raise questions with my doctor about this study.
All my questions were answered satisfactorily.
I know the possible risks and benefits of participating in this study.
I understand that participation in the study is voluntary and I confirm that I have had sufficient time to consider this and understand that:

- I can consult my doctor for more information at any time.
- I can withdraw from this study at any time without discrimination or retaliation, and my medical treatment and rights and interests will not be affected.

I also know that if I drop out of the study, especially if I drop out of the study due to drugs, if I tell the doctor about my condition change and complete the corresponding physical examination and physical and chemical examination, it will be very beneficial to the whole study.
If I need to take any other medication due to a change in my condition, I will consult my doctor beforehand or tell him the truth afterwards.
I agree with the ethics committee of the drug regulatory agency or the sponsor's representative to access my research materials.
I will receive a copy of the signed and dated informed consent form.
In the end, I decided to agree to participate in this study, and promised to follow the doctor's advice as much as possible.

Patient signature: _ _ _ _ _ _ _ _ _ _ _ _ _ _ DATE: _ _ _ _(YYYY-MM-DD)
Contact number: _ _ _ _ _ _ _ _ _ _ _ _ _ _ _ _

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

Signature of doctor: _ _ _ _ _ _ _ _ _ _ _ _ _ DATE: _ _ _ _(YYYY-MM-DD)
Contact number: _ _ _ _ _ _ _ _ _ _ _ _ _ _