Supplementary file 2: Informed Consent

Informed Consent

Dear patient:

If you were diagnosed with colorectal cancer who have been scheduled for laparoscopic surgery, we invite you to participate in this study aiming to evaluate the efficacy of preoperative acupuncture for management of POI. You need to decide whether you want to participate or not. It is helpful for you to introduce about the study aim, procedures, benefits and risks of the study, inconvenience and potential discomforts during the study. This study is supported and funded by National Science Foundation for Distinguished Young Scholars (NO.81825024). Carefully read the following and feel free to ask the study doctor any question which you may have.

Why is this study being done?

Postoperative ileus (POI) which is one of the most common postoperative complications. POI is characterized by delayed gastrointestinal (GI) recovery, including abdominal distension, delayed passage of flatus and stool, inability to tolerate oral food. Many measures to reduce POI have been explored, including nasogastric tube for sputum aspiration, venous transfusion, parenteral nutrition and restoring gastrointestinal motility through simple exercise. But there are problems

with these treatments, such as side effects. Acupuncture is traditional Chinese medicine, which dates back more than 3,000 years. In recent years, the use of acupuncture as a treatment to the management of various gastrointestinal motility problem has gained increasing popularity worldwide.

Aim of the study

The aim of this study is to estimate the efficacy of preoperative electroacupuncture (EA) and sham electroacupuncture (SA) in reducing the time to first defecation with the ERAS protocol.

You will randomly be allocated to one of two groups:

A) Electroacupuncture Protocol

B) Sham electroacupuncture Protocol

Who should be in this study?

Patients who meet the criteria will be included in this study if they have the following:

(1) male or female patients aged>18 years.

(2) patients diagnosed with colorectal cancer who have been scheduled for laparoscopic surgery.

(3) patients with American Society of Anesthesiologists grades18 I-III.

(4) patients who sign the informed consent.

Patients will not be included in this study if you have the following:

(1) patients who received epidural anesthesia.

(2) patients whose laparoscopic surgery should be synchronized with other organs resection.

(3) patients who require conversion from laparoscopic surgery to open surgery or underwent total colorectal resection.

(4) patients with intraoperative and postoperative complications requiring long-term (> 1Day) intensive care; patients who require stoma creation.

(5) patients with a history of mental disorders or alcohol or drug abuse.

(6) patients who have been receiving acupuncture treatment within 1 month prior to the study.

(7) patients with electrical stimulation devices (pacemaker or implantable defibrillator).

(8) patients who have participated in other clinical studies.

How many POI patients will participate in the study?

We plan to recruit 80 patients.

Do you agree to biological sample collection during operation?

A) Yes

B) No

What risk effects may happen to me by participating in the study?

Acupuncture is a relatively safe procedure and few side-effects have been reported. You may feel nausea, dizziness and fainting during or after acupuncture treatment. Bleeding, hematoma, and other phenomena may occur after acupuncture treatment, but these phenomena will release and disappear after a few days of acupuncture treatment. If you feel any discomforts during the treatment, you need to tell your doctor about your conditions immediately and then the doctor will evaluate the condition and give you appropriate medical treatment.

What benefits can I expect?

Patients may benefit from a reduction in POI symptoms and promote postoperative recovery after EA treatment. The information will be beneficial in the management of other patients with a similar condition in the future. If you decide to participate in the study, you will get the study treatment for free during the study period.

Can I refuse to be in the study?

Whether you participate in this study or not is depending on your desire totally. You can choose not to take part in the study, or you can drop out at any time without your doctor permission during the study. If you quit the study, you will receive the standard treatment as other patients at our department clinic.

Confidentiality and privacy

All information about patients will be kept confidential by the research group members. Only the clinical research members who responsible for the study may have access to your medical records. Your name will not appear in any publication or report related to this study. We will make every effort to protect the privacy of your personal information.

How to acquire correlative information of the study?

If we notice any new information that may affect your decision to continue participating in the study, the doctor will keep you informed.

If you have any questions related to the study, please contact to Doctor * (Tel: ********).

If you have any questions related to your personal benefits, you can consult the Ethics Committee of *** Hospital (Tel: ****

I have read and understood this consent form. All my questions have been answered. I volunteer to take part in this study.

Patient's signature Patient's name Date

_____ _____ _____

Site Investigator’s signature Site Investigator’s name Date

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