

**Electrical Acupoint Stimulation for Postoperative Recovery in Elder
Patient Undergoing Knee Arthroplasty: Study Protocol and Statistical
Analysis Plan**

**(Code name: LINGSHU)
Clinical trial protocol**

**Responsible party: Affiliated Hospital of Shandong University
of Traditional Chinese Medicine**

Study main investigator: Su Fan

Anticipated data: may 1, 2018

Protocol number: SZH-A-20170501-R2

Informed Consent Form

1 Introduction of Research Project

Obviously, the anesthetic agents and surgical operation could be harmful to patients, not only a series of operation relevant situation happen but also some postoperative complications such as urinary retention, deep vein thrombosis, mental disorder, et al, which really bother the patients received a surgery.

The traditional Chinese medicine is really care about the status of physical organs function. The process of anesthesia and surgical operation must cause some bad effect on patients, which include imbalance of Qi and Blood according to the theory of traditional Chinese medicine, then the postoperative complications might show up. In this study, it will prevent the postoperative complications under this theory and improve the recovery of patients through the intervention stimulating acupoints, they are zusanli, sanyinjiao, neiguan, quchi. The aim of the intervention will result to regulate the Qi and Blood, then match them finally.

2 The Purpose

Observed the postoperative complications after transcutaneous electrical acupoints stimulation.

3 Method

You will divide into different group, in which accept differ interventions. No matter what intervention, you are safety, only you can do is compare

with our physician as follows:

- (1) tell all about the medical history of you to your doctors, accept relevant lab or physical examinations;
- (2) the intervention is not harmful to your body, but might lead to some uncomfortable feelings, communication with your doctors completely.

4 Adverse Event

The intervention is not harmful to your body, theoretically, while might cause to some rash or edema locally, all doctors beside you will notice about this and the fee relevant will be covered by our study.

5 Benefit from the Study

According to our protocol, when you are chosen to attend this research, we promise that you will be taken care very well, receive all examinations for free, support and serve you as our family members.

6 Leave the Research

you have to make sure that you attend this study totally voluntary, you will be treated well within the study and never get bad effect withdraw the study.

7 Research Consulting

you can call the doctors relevant the research anytime if confused to treatment measures or benefit or right.

8 Confidentiality

During all course of observation, your identity and research data will be

kept secret, only relevant research units could obtain these data within permission. Your research results probably be published confined to study, and your identity will never open to public.

9 procedure

Firstly, the participants are grouped according to the random numbers prepared, collect all relevant data before surgery and fill CRF1-4. The participant are transfer to operation room, the intravenous infusion built in there, monitoring the participants included ECG, HR, BP, RR, SpO2, EtCO2, then the intervention will be administered. Next after the epidural anesthesia administration, the surgery will start, check the patients intraoperatively and fill CRF-5. On the first day after surgery, check the patients and fill CRF-6, on the third day after surgery, check the patients and fill CRF-7, on the 7th day after surgery, check the patients at and fill CRF-8. Finally, collect all data after surgery included lab test, image examination, visit result, primary outcome measures, secondary outcome measures, adverse events for data analyzed.

If you have understood the content above, and decided to attend this study, please sign below:

Subject signs full name here: _____

Subject address: _____

Subject telephone number: _____

Date: _____

The relevant doctors will responsible for explaining all rights and risks to the volunteers.

The relevant doctor signs full name here: _____

The relevant doctors telephone number: _____

Ethics committee of affiliated of Shandong university of traditional Chinese medicine. Contact number: 086-0531-68616733.