Transcutaneous Electrical Acupoint stimulation used in Peri-operation for preventing postoperative complications, safety and effectiveness of randomized, Single-blind, clinical trial

(Code name: LINGSHU)
Clinical trail protocol

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

Study main investigator: Su Fan

Anticipated data: Aug, 2017

Protocol number:  SZH-A-20170501-R2
**Background**

The pathophysiological process during a surgery is extremely complicated, especially for elder patients. The traditional Chinese medicine consider that the Qi and Blood are the base of life activity, more than that, to keep them balance might be more important for organs working well. Actually, a surgery will consume Qi and Blood, which perhaps cause to one or both of them shortage, then imbalance of them appear. According to the theory of traditional Chinese medicine, transcutaneous electrical acupoint stimulation administration ahead of surgery can regulates and supports the Qi, making a balanceable situation of Qi and Blood. As results, the organs will be functional well under the balance of Qi and Blood, to avoid all category of postoperative complications.

**Study aim**

To evaluate the safety, effectiveness, and adverse reaction of the transcutaneous electrical acupoint stimulation administration in peri-operation for preventing postoperative complications through working on zusanli, sanyinjiao, neiguan, quchi.

**Study design**

Prospective, Randomized, Single blind, Clinical trail.

**Announcement**

This study was approved by the ethic committee of affiliated hospital of Shandong traditional Chinese medicine.

**Subjects**

The participants enrolled to the clinical trail have no limitation on gender, anyone could be the subject only if fit to the inclusion criteria and exclusion criteria. The inclusion criteria included agree to informed
consent form, age range from 65 to 85 years, plan to receive total hip or knee arthroplasty. And the exclusion criteria include that the age under 65 or beyond 85, forbidden to administration of transcutaneous electrical acupoint stimulation, communication disorder, emergency surgery, patients with medical history of mental disease, cerebrovascular disease, patients with operative history of heart, brain, lung, patients had attended some clinical trails else in the past three months.

**Case number estimated:** Total 99 cases.

**Method**

All participants divided into 3 groups. They are group acupoint stimulation (AS), group non acupoint stimulation (NAS), group non stimulation (NS). They are totally different at receiving intervention. The intervention stimulates on acupoints included zusanli, sanyinjiao, neiguan, quchi through transcutaneous electrical stimulation, started from 30 minutes before operation until 30 minutes after operation. Stimulus intensity: depend on the maximal tolerance of participant. Stimulus frequency: 2/10 HZ. Each group accept administration differently, in group AS, participants receive transcutaneous electrical stimulation on acupoints zusanli, sanyinjiao, neiguan, quchi, which are located standardly on ST36, SP6, PC6, LI11, separately. For group NAS, although the participants receive transcutaneous electrical stimulation but stimulus point are bony promontory beside the acupoints, while in group NS, the participants accept only connection to electrode sheet on acupoints but without stimulation.

**Research indices:**

Primary outcome measure: the main postoperative complications during 7 days and the numbers

Secondary outcome measures: the incidence of postoperative nausea
and vomiting during 3 days, the incidence of postoperative urinary retention during 3 days, the change of postoperative stress response during 5 days, the incidence of postoperative cognitive dysfunction during 9 days, the incidence of postoperative deep vein thrombosis during 7 days, the incidence of postoperative pneumonia during 7 days, the change of postoperative inflammatory responding during 9 days, the change of postoperative function of liver and kidney during 9 days, length of stay and cost, and the adverse event in entire trial.

**Trail span:** from 1 day before surgery to 7 days after surgery.

**Sample size estimation**

According to sample size calculating formula ($\alpha=0.05$, $\beta=0.1$) and the standard deviation result from past trails, add 20% lost sample size, the final participants estimated are 99 cases, who divided into 3 groups. They are group acupoint stimulation, group non acupoint stimulation, group non stimulation.

**Randomized administration**

The randomized process depends on SAS software. All participants divided into 3 groups randomly, which run by SAS software to obtain random numbers of subjects. The numbers will be enveloped and stored by a special person, who will open the envelop once meeting the right participant and going on the clinical trial observation.

**Statistical analysis plan**

The enrolled participants’ variables are collected for Homogeneity of variance test, these variables included gender, age, ASA, weight, height, BMI, surgical information and medical historic diseases. The data could be enumeration data or measurement data. The measurement data will be expressed as Mean ± standard, while enumeration can be describe as
ranked data. Under the Homogeneity, for the enumeration data, Repeat Measures data analysis of variance is used and Rank Sum Test for Multi Group Comparison is used to analyze measurement data. All $p < 0.05$ is considered as statistically significant.

**How to blind:**

The participants in trail have no experience of transcutaneous electrical acupoint stimulation. Both side of all participants are placed electrode sheets on acupoints included zusanli, sanyinjiao, neiguan, quchi. Test the tolerance of participants by stimulus intensity, then keep frequency and intensity through the whole process of the surgery.

The participants grouped by an assigned researcher, who will only be responsible for this work.

The researcher, who administered the intervention, will not participate data collection and data analyzed.

The data collected by an assigned researcher, who only do this work. The data are analyzed by the third organization.