Electroacupuncture for postoperative pain after nasal endoscopic surgery: study protocol for a pilot randomized controlled trial

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Study protocol

Keywords: Electroacupuncture, postoperative pain, nasal endoscopic surgery, RCT, randomized controlled trial, clinical trial

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Abstract

Background: Postoperative pain is a common disorder that interferes with the quality of sleep after nasal endoscopic surgery and delays postoperative recovery. Acupuncture is an effective tool for pain management. However, electroacupuncture specifically for the relief of postoperative pain after nasal endoscopic surgery has not yet been studied through a randomized controlled trial.

Method/Design: A pilotrandomized, sham-controlled, patient- and- assessor-blind trial is designed to evaluate the efficacy and safety of electroacupuncturein managing postoperative pain following nasal endoscopic surgery of sinusitis with nasal polyps. There will be 30participants randomly allocated to an electroacupuncture or non-invasive sham control in a 1:1 ratio. Treatment will be done within 2 hours before operation, immediately after the operation upon arrival to the recovery ward, and once daily for 3 days. The primary outcome of the Pain Numerical Rating Scale (NRS) will be analyzed using the area-under-the-curve (AUC) method. The secondary outcome measures include Heart Rate (HR) and Blood Pressure (BP) after operation, the sleep quality during the hospital stay (Actigragh),Quality of Recovery-15 (QoR-15), and the MOS item short form health survey (SF-36). ITT analysis will be used in this RCT.

Discussion: This pilot randomized controlled trial will explore the feasibility of further clinical application for the management of postoperative pain using electroacupuncture treatment, and it will inform the design of a further full-scale trial.

Trial Registration: Chinese Clinical Trial Registry, ChiCTR1900024183, Date: 2019-06-29.
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Keywords: Electroacupuncture; postoperative pain;nasal endoscopic surgery; RCT; randomized controlled trial; clinical trial

Background

Postoperative pain is a major symptom following nasal endoscopic surgery for sinusitis with nasal polyps. Effective management of postoperative pain after nasal endoscopic surgery is especially important for patient recovery. Pain due to nasal filling may interfere with deep breathing, sleep quality, and patient satisfaction. According to previous reports, a failure to treat acute pain immediately may cause long term chronic pain[1, 2]. Effective relief of acute pain is a challenge for patients and physicians following a nasal endoscopy. Analgesic drugs, especially opioid analgesics, are usual used to relieve pain after surgery. However, there are some risks of side-effects such as respiratory depression and drowsiness, which can lead to a delayed postoperative recovery. Thus, its urgent to seek a safe and effective treatment to control postoperative pain and limit recovery time.

Acupuncture therapy has been widely used for pain relief, with its analgesic effect having been reported worldwide. There are several studies that have shown that acupuncture can relieve pain after surgery, including oral surgery[3, 4], cardiac surgery[5], laparoscopic cholecystectomy[6-8], gynecological

surgeries[9, 10], back surgery[11] and nasal surgery[12]. Therefore, we deduce that acupuncture can potentially be used to relieve postoperative pain following a nasal endoscopic surgery. Despite the positive results published by these previous studies, the results are not dependable due to an improper sample size, inappropriate randomization and lack of blinding. Therefore, high quality evidence is needed to support the previous findings and form the protocol for the use of acupuncture for postoperative pain in clinic.

For those reasons, we design a randomized controlled trial using an appropriate randomization, rigorous allocation concealment, and blinding, to examine the efficacy of electroacupuncture in relieving postoperative pain after nasal endoscopic. We aim to confirm that electroacupuncture may be useful to relieve postoperative pain after nasal endoscopic and minimize postoperative recovery time. The findings of the study will provide high quality evidence and create a standard protocol for clinical application of electroacupuncture as treatment for postoperative pain after nasal endoscopic surgery.

We hypothesize that Electroacupuncture (EA) is effective, safe and feasible to be used for postoperative pain management after nasal endoscopic surgery.

Methods

Study design:

This is a pilot, single-site, patient-assessor-blinded, placebo-controlled, randomized clinical trial which will be carried out in Shanghai Municipal Hospital of Traditional Chinese Medicine. Eligible patients will be randomly divided into the EA group and the SEA group in a 1:1 allocation ratio. All patients will sign the informed consent before proceeding with the trial. The flowchart of the study process is detailed in Figure. 1.

Figure. 1. Flowchart of this study

Sample size:

This is a pilot study. In the relevant literature, no previous studies have utilized either the same evaluation method as the main solution index, the comparison method or the degree of intervention. Therefore, we are unable to formally calculate a statistical power. The appropriate sample size for a 2-arm pilot study should be more than 12, considering we assume a 20% dropout rate, each group will take 15 cases. We will therefore recruit a total of 30 individuals for this randomized controlled trial (RCT)[13-15].

Recruitment:

This pilot randomized, sham-controlled, patient-assessor-blinded trial will be recruited in the Shanghai Municipal Hospital of Traditional Chinese Medicine. Eligible subjects who have been scheduled for nasal endoscopic surgery for sinusitis with nasal polyps will be invited to participate in this study. Participants will be referred from an ENT (ear -nose-throat) doctor, and then a research assistant will screen the

patients and obtain written informed consent. Following the consent, eligible participants will be randomly allocated to either the electroacupuncture group or sham electroacupuncture e group. All participants will undergo a standard operative procedure and receive postoperative treatment. Treatment will be given within 2 hours prior to the surgery, immediately after surgery arrival to the recovery ward and daily treatment following surgery for 3 days. NRS assessments will be conducted after arrival to ward, every hour for 6 hours, and other secondary outcome measurements will be taken once per day until discharge. The assessment schedule is detailed in Table. 1.

Table. 1. Schedule of enrolment, intervention and assessment

Inclusion Criteria:

Patients who meet the following criteria will be included:

1) Patients with an American Society of Anesthesiologists (ASA) physical status I to II;

2) Eligible for nasal endoscopic surgery, including Sinusitis with nasal polyps;

3) Age is 18-60 years old;

4) Capable of understanding and providing responses about the outcome measurement;

5) Agree to participate in the survey and sign a written informed consent form.

Exclusion Criteria:

Patients who meet the following criteria will be excluded:

1) Having chronic pain currently requiring treatment by an opioid or nonsteroidal anti-inflammatory drug medication;

2) Having severe psychiatric disease and cognitive impairment and not able to sign the consent;

3) Having hepatitis B, hepatitis C, HIV or syphilis;

4) Having a history alcohol or drug abuse;

5) Having local or systemic infection;

6) History of acupuncture experience in the past 6 months.

Randomization and Allocation concealment

The random sequence will be conducted by block randomization using the SPSS version 23.0 software by an independent research assistant. After the participants complete the screening process and baseline assessment, they will be randomly assigned to 1 group in a 1:1 ratio. The random sequence will be kept

in the opaque envelopes. The treatment allocation codes will not be revealed before the first treatment. In an effort to minimize breaks in coding, the principal investigator who designed the trial and research personnel who perform the outcome assessments will also be blinded to the treatment assignment.

Blinding:

Before the beginning of treatment, we will tell the participants that they have the same possibility of being assigned to the electroacupuncture treatment or electroacupuncture -like simulation treatment. In order to ensure the implementation of the blinding method, the acupuncturist will require the participant to wear the eye-patch before they receive treatment. Therefore, there is no one would know the treatment allocation before the initial treatment. Only the acupuncturist who performs the treatment will know the group allocation at the time of treatment (the principal investigator, the data analysts, the outcome assessors and statistician) will remain blinded.

Quality control:

The pre-job training and examination of acupuncture treatments will be performed by the principal investigator (Dr. SF Xu) to ensure the quality of this trial. This includes the inclusion and exclusion criteria, location of the acupoints and the depth of needling. In addition, the data management and outcome measures and statistical analysis will be completed by 3 independent researchers.

Intervention protocol:

The electroacupuncture treatment will be performed within 2 hours before surgery, immediately after surgery in the recovery ward and every 24 hours after the surgery for 3 days (5 treatments sessions in total). In each treatment session, every patient will be in a separate space and wear an eye-mask. Acupuncturists must be registered, holding a Master's degree and have at least 3 years' experience in acupuncture practice. The treatment methods of electroacupuncture and acupoints are shown in Table. 2.

Table. 2. Treatment methods of electroacupuncture and acupoints

The electroacupuncture group

Preoperative electroacupuncture treatment and acupoint justification

The operation preparation begins 1 day before the operation, participants will be asked to fast from 8 hours before the operation. Participants will receive the 1st electroacupuncture treatment within 2 hours prior to the surgery.

We will perform the electroacupuncture procedure following the Guidance of Clinical Practice of Acupuncture[16]. Participants will be placed in the supine position at a separate space and asked to wear an eye-mask to prevent the patient from watching the treatment procedure. The researcher will sterilize the patient's skin with 75% alcohol wipes before the treatment. Each acupuncture needle will be standard

stainless steel, sterile, and disposable (0.25 × 40 mm and 0.30×40mm in length; Jia Jian, China). All patients will receive treatment at 17 standard acupuncture points: bilateral Hegu (LI4), Neiguan (PC6), Shenmen (HT7), Yingxiang (LI20), Zusanli (ST36), Shangxing (GV23) in all sessions. In addition, Baihui (GV20), Yintang (GV29), Anmian (EX-HN22) and Sanyinjiao (SP6) will be used in postoperative electroacupuncture treatment. All acupoints were selected according to the textbook, literature and clinical experience. The acupoints which we have selected will be located with reference to the acupuncture textbook of the International Standard Library of Chinese Medicine written by Zhang, Zhao, and Lao[17]. First the researcher will manipulate manually until the patient reports needling sensations (Deqi sensation). An electric stimulator (HANS-200B) will be connected to 3 pairs of needles: LI4-ST36 (bilaterally), GV20-GV23, using continuous wave type, low-frequency, 2-HZ and an intensity of 2 mA. Each treatment session will last for 30 min. After the removal of needles, the researcher will use a clean cotton wool to prevent bleeding by compressing the points. In the first treatment, 11 acupoints will be used and 17 acupoints will be used in the postoperative treatment. The acupoint selection and rationale are summarized in Table. 3.

Table. 3: The acupoint selection and rationale based on Traditional Chinese Medicine (TCM).

Preoperative electroacupuncture treatment and acupoint justification

Participants will be transferred to the ward within 30 min after the operation. They will receive the electroacupuncture treatment immediately upon arrival in the ward. Then, the participants will receive electroacupuncture treatment every 24 hours after the operation over the following 3 days. The electroacupuncture treatment will be the same as the preoperative electroacupuncture treatment described above, except that we will add the following 6 points: Baihui (GV20), Yintang (GV29), Anmian (EX-HN22) and Sanyinjiao (SP6).

The control group:

In the control group, Streitberger Placebo needle, a sham acupuncture device that has been widely reported and validated will be used[18]. The non-invasive sham needles will be performed 1.5 *cun* lateral and posterior to the true acupoints[19, 20]. The blunt tip of the sham needles will touch the surface of the skin but no penetration. The electric stimulator (HANS-200B) will be set beside the patients and 3 pairs of electrodes will be connected to the LI4-ST36 (bilaterally), GV20-GV23 for 30 minutes but no electrical current will be delivered.

Outcome measures

The participant's recovery will be monitored during and after the operation. The primary outcome will be to assess participants' postoperative pain scores by Numerical Rating Scale (NRS) hourly for 6 hours after surgery, then daily for 3 days after the operation. The secondary outcomes include the following: Heart Rate (HR) and Blood Pressure (BP) after operation, the sleep quality during the hospital stay (Actigragh), Quality of Recovery-15 (QoR-15) and MOS item short form health survey (SF-36). If the

participants are unable to be managed according to the protocol for any reason including side effects, no further data will be collected. The assessment schedule is detailed in Table 1.

Primary outcome

Numerical Rating Scale (NRS):

NRS is a commonly used scale for assessing clinical pain. It is easier for patients to grade pain intensity with numbers rather than other measurements like the Visual Analog Scale. The NRS is a 0-10 points scale for pain, 0 indicating no pain and 10 indicating worst possible pain. NRS pain scores will be assessed hourly for 6 hours after surgery, then daily for 3 days[21, 22].

Secondary outcomes:

Heart Rate (HR) and Blood Pressure (BP):

The HR and BP will be monitored during and after the operation, which has been extensively utilized and validated to assess the patients' vital signs. HR and BP will be assessed hourly for 6 hours after surgery, then daily for 3 days.

Actigraphy assessments:

The actigraphy is a wrist watch which can monitor patients' sleep quality when worn on the wrist overnight. The main sleep indexes are sleep efficiency (SE), total sleep time (TST) and sleep awakenings (SA). The analysis of sleep condition and sleep quality will be performed by the software ActiLife6 (Version 6.8.1, Actigraph LLC) [23]. The Actigraphy assessment will be assessed 5 times: the night before the operation, the night of operation day and three night after operation until discharge.

Quality of Recovery-15(QoR-15):

The QoR-15 is a valid, extensive and efficient evaluation of patient's postoperative recovery. The QoR-15 scale measures patients' recovery from 5 aspects: pain, physical comfort, physical independence, psychological support, emotional state. The questionnaire consists of 15 items, with a score of 0 to 10, 0 representing no presence, 10 representing always present. The sum of the scores is the patient's QoR-15 score[24]. QoR-15 will be assessed 2 times which are: after surgery and day of discharge.

The MOS item short from health survey (SF-36):

The SF-36 consists of 36 items which are summated into 8 multiitem scales: physical functioning (PF), role-physical (RP), bodily pain (BP), general health (GH), vitality (VT), social functioning (SF), role-emotional (RE), and mental health (MH) and 1 single-item scale on health transition. Higher scores represent better health status[25]. SF-36 will be assessed 2 times which are: after surgery and day of discharge.

Safety assessment:

Reasons for drop out

When a participant drops out before completing the study, the reasons for drop out will be recorded. We will terminate the treatment if there are serious adverse effects.

Adverse events

Participants will be informed the potential adverse events related to acupuncture procedure such as bruises, hematomas, infection, pain, during the signing of inform consent. Adverse events will be graded into: grade 1, mild, grade 2, moderate, grade 3, severe or medically significant. Any adverse events that occur during the trial will be recorded by the patients and doctors. Vital signs will be assessed at the time of the event, including Heart Rate, blood pressure and respiratory rate. All details of adverse events will be reported in the Case Report Form. If any severe adverse event (SAE) occurs, the Clinical Research Center of Drugs of the Shanghai University of Traditional Chinese Medicine will discover the blind, reveal the code of this participant in order to determine the correlation of the SAE with the intervention, and make the final decision as to whether to continue the study or not. We will analyze the influence of all events at the end of the trial.

Credibility of Treatment Rating Scale (CTRS)

We will use the Credibility of Treatment Rating Scale (CTRS) to assessed the credibility of the acupuncture treatments[26, 27]. It consists 4 items and is used to assess the participants' "perceived logic of the treatment," "confidence in recommending the treatment to their friends who have similar complaints, "confidence in the treatment to alleviate their complaint," and "likelihood that the treatment would alleviate their other complaints."

Blinding success assessment

After the final treatment is completed, we will test the success of blinding by asking the participants the following question "When you volunteered for the study, you were informed that you had equal odds of receiving traditional electroacupuncture or electroacupuncture-like simulation treatment. Our study is complete, which electroacupuncture do you think you received?" 3 choices will be provided for participants: electroacupuncture treatment group, electroacupuncture-like simulation treatment group and uncertain. If participants do not chose uncertain, we will ask the reason why they have made that assumption[28].

Monitoring:

To ensure the quality of this trial, the whole process will be conducted under the supervision of a qualified clinical trial expert and be carried out by Shanghai Municipal Hospital of Traditional Chinese Medicine. The Clinical Research Center of Drugs of the Shanghai University of Traditional Chinese Medicine will

provide data monitoring with access to any interim results. It also identifies problems in the project, if any; the center makes the decisions to change the details of this protocol and announce the persons conducting the trial by written notice after approval by the application ethics committee. In addition, a qualified clinical trial expert will be invited to monitor this study and the PI will take full responsibility and will make the final decision.

Data management:

ResMan research Manager of the Clinical Trial Management Public Platform will be used to manage the original data, and the original data will be collected by blinded assessors and double-entered. The system will be tested and the relevant users will be trained before it is officially launched. Only the relevant personnel will receive the account number and password. The original data will be entered within 1 week of the participants finishing the all of the treatments. If the data is found to be uncertain, the data supervisor will notify the researcher to respond with a data question form. If necessary, the statistician will send a data question form to the researcher and the researcher's answer should be filled in the form. The question form is returned to the statistician by the inspector. The clinical supervisor will monitor the work of the clinical trial center at least once a month.

Statistical analysis:

An independent statistician blinded to group allocation will perform statistical analysis and the Intention-to-Treat (ITT) analysis. All data will be carried out by statistical software SPSS 23.0 for Windows, including the data from any participants who have dropped out of the trial. We will use multiple imputation to address any missing data. All demographic and clinical characteristics of the subjects (such as sex, age, and weight) will be processed based on descriptive analyses. We will identify the homogeneity of demographic characteristics and study variables between two groups. Quantitative data will be done as mean ± standard deviation for continuous variables while the qualitative data will be presented as the frequency and percentage. To analyze the primary outcome, area-under-the-curve (AUC) of the NRS pain scores will be calculated by plotting on the timescale using the trapezoidal method, and comparisons between groups will be made using the Student’s t test. For the secondary outcomes, blood pressure (BP), Heart Rate (HR), QoR-15, SF-36 and Actigraphy assessments (TST, SA and SE) between the 2 groups will be compared with Student’s t test or the Wilcoxon rank-sum test. All reported *P* values will be 2-sided, and a *P* value of less than 0.05 is considered statistically significant.

Discussion

Postoperative pain is a common disorder that interferes with the quality of sleep after nasal endoscopic surgery and delays postoperative recovery. It is also a significant individual burden. We chose to study with acupuncture because previous studies have shown that acupuncture is effective and safe treatment for pain management[11, 29-31]. If the postoperative pain is not treated immediately, patients can develop long term chronic pain. However, electroacupuncture specifically for relief of postoperative pain after nasal endoscopic surgery has not yet been studied through a randomized controlled trial.

This study protocol will be conducted at the Shanghai Municipal Hospital of Traditional Chinese Medicine. Acupuncture has already been used for inpatients. However, it has not been used for the immediate analgesia of a surgical patient. This study is designed to investigate the efficacy and safety of using acupuncture as an adjunctive therapy for postoperative pain and discomfort. If this study protocol confirms that acupuncture is effective and safe, it can be implemented as a new standard for relieving postoperative pain in Chinese and Western medicine.

There are several challenges and limitations in this study protocol. Firstly, patients with different types of nasal disease will be screened to reduce variability within the study population. Therefore, only participants who need nasal endoscopic surgery for sinusitis with nasal polyps will be included. In addition, randomization will be done rigorously so that the participants in the 2 groups can be balanced. Secondly, preoperative treatment must be carried out in the recovery ward within 2 hours before the operation. According to our research, there are many studies that have shown that acupuncture was performed before the induction of anesthesia in the operating theater [6, 32, 33]. However, the surgical team worried that that will lengthen the interval time. Therefore, the preoperative treatment time may not be ideal. Thirdly, it is difficult to schedule the acupuncture treatment because the surgery time is uncertain. To solve this problem, the acupuncturist will wait until the surgery has ended and perform the postoperative treatment immediately. In addition, the exact operation and each treatment time will be recorded for analysis. Fourthly, because of the nature of clinical trials of acupuncture, it is inevitable that the acupuncturist knows the treatment allocation. However, the acupuncturists will not know nothing about the results. In order to prevent the acupuncturist from accidentally revealing the group allocation, their interactions with the patients will be limited. All patients will wear an eye-mask while receiving treatment and be arranged in separate spaces. Overall, blinding will be strictly enforced to balance the efficacy between the 2 groups.

Though there are many difficulties, we will strive to standardize the steps of the study to ensure its quality. We hope this pilot randomized controlled trial will provide clinical evidence for the feasibility of electroacupuncture for alleviating postoperative pain, and the outcomes will inform the design of a further full-scale trial.

Trial Status

The first investigators' meeting took place on 31 May 2019. The RCT is in preparation now and will launch on September 1st, 2019. Recruitment is expected to end in late 2019.

Abbreviations

AUC: Area-Under-the-Curve

EA: Electroacupuncture

SEA: Sham electroacupuncture

NRS: Pain Numerical Rating Scale

SA: Sleep Awakenings

TST: Total Sleep Time

SE: Sleep Efficiency

QoR-15: Quality of Recovery-15

SF-36: MOS item short from health survey

BP: Blood Pressure

HR: Heart Rate

RCT: Randomized Controlled Trial

ENT: Ear -Nose-Throat

ASA: American Society of Anesthesiologists

HIV: Human Immunodeficiency Virus

CTRS: Credibility of Treatment Rating Scale

NIH: National Institutes of Health

ITT: Intention- to-Treat

SAE: severe adverse event

Declarations

Ethics approval and consent to participate:

This RCT is approved by the Ethics Committee of Shanghai Municipal Hospital of Traditional Chinese Medicine on June 06, 2019 (certificate number 2019SHL-KY-15). The final version identifier of this protocol is 1.1, which is modified on 10 May 2019.

The purpose, procedures, and potential risks of the RCT will be explained clearly to the participants. All participants shall give their written informed consent to the research assistant before joining the RCT.

Consent for publication:

Not applicable.

Availability of data and material:

The trial results will be published as peer-reviewed scientific papers and poster or oral presentations in conferences. All data and protocol will be available beginning 3 months and ending 3 years following publication of the results. The trial data will be available from the corresponding author upon reasonable request.

Competing interests:

The authors declare that they have no competing interests.

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Authors' contributions:

The trial is designed and developed by SFX, HGW and LXL. The manuscript is drafted by SSL. The protocol is carefully revised, edited by SSL and QZ. XY, HYY, and ZJZ contributed the discussion. All authors read and approved the final manuscript.

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Tables

Table. 1. Schedule of enrolment, intervention and assessment

	STUDY PERIOD				
	S B O	Preoperative period		Postoperative period	
TIMEPOINT		*Within 2 hours before operation*	*Upon recovery*	*hourly for 6 hours after surgery*	*Once daily until discharge*
Basic information					
Informed consent	X				
Inclusion/Exclusion	XX				
Medical history	X				
Vital signs	XXX	X	X	X	X
Interventions					
EA		X	X		X
Sham EA		X	X		X
Assessments					
Primary outcome					
NRS			X	X	X
Secondary outcomes					
	X	X	X	X	X
HR & BP	XX				X
Actigraphy			X		X*
QoR-15			X		X*
SF-36					
Others					
Adverse events	X	X	X	X	X
Patients's satisfaction					X
Success of blinding					X

Abbreviations: S: Screening, B: Baseline, O: Operation, NRS: Numerical rating scale, HR: Heart Rate, BP: Blood Pressure, QoR-15 Quality of Recovery - 15, SF-36: Short From health survey.

* Conduct at day of discharge

Table. 2. Treatment methods of electroacupuncture and acupoints

	EA group	Sham EA group
Acupoints	LI4, PC6, HT7, LI20, ST36, GV23 in all sessions, GV20, GV29, EX-HN22, SP6 in postoperative treatment.	LI4, PC6, HT7, LI20, ST36, GV23 in all sessions, GV20, GV29, EX-HN22, SP6 in postoperative treatment.
Depth of insertion	HT-7, GV20, GV23, GV29, LI4, LR3 10mm LI20, SP6, PC6, ST36 30mm	No insertion
Needle type	Steel needle (Wuxi Jiajian Medical Co. Ltd. Wuxi, China)	Blunt-tip needle (Streitberger Placebo-needle)
Needle sensation	With de-qi sensation	Without de-qi sensation
Electric stimulation	Needle on 3 pairs of needles: LI4-ST36（bilaterally）, GV20-GV23 connected to an electric stimulator (HANS-200B) using continuous wave type, low-frequency, 2-HZ and intensity of 2.	Needle on 2 pairs of needles: LI4-ST36（bilaterally）, GV20-GV23 connected to an electric stimulator (HANS-200B). no electrical current deliver

Table. 3: The acupoint selection and rationale based on Traditional Chinese Medicine (TCM)

Acupoint	Location	TCM indication	Suggested technique
LI4 *(Hegu)*	Dorsum of hand, at the level of the midpoint of the second metacarpal bone, between first and second metacarpal bones	Helps in abdominal pain.	Needle perpendicularly 0.5–1.0 *cun*
PC6 *(Neiguan)*	Palmar aspect of the forearm, between the tendons, 2 *cun* away from the transverse crease of the wrist	Luo (Connecting) point of the Pericardium meridian, helps in gastric pain and calming the Shen	Needle perpendicularly 0.5–1.5 *cun*
HT7 *(Shenmen)*	Palmar aspect of the wrist, ulnar end of the transverse crease	Shu (Stream) and Yuan (Source) points of the Heart meridian, helps in calming the Shen (spirit)	Needle perpendicularly 0.3–0.5 *cun*
LI20 *(Yingxiang)*	0.5 *cun* lateral to the midpoint of the border of line ala nasi, in the nasolabial groove	Nasal congestion, epistaxis, wry face; Biliary ascariasis	Needle perpendicularly 0.3–0.5 *cun*
ST36 *(Zusanli)*	Antero-lateral leg, 1 middle-finger breadth next to the anterior crest of tibia, 3 *cun* under the depression lateral to the patellar ligament	Stomach's lower He point, helps in regulating Qi and blood circulation.	Needle perpendicularly 0.5–1.5 *cun*
GV23 *(Shangxing)*	1 *cun* directly above the midpoint of the anterior hairline	Headache, eye pain, rhinorrhea, epistaxis; Febrile disease, malaria; Manic psychosis	Needle perpendicularly 0.5–1.0 *cun*
GV20 *(Baihui)*	5 *cun* directly above the midpoint of the anterior hairline, at the midpoint of the line connecting the apexes of the two auricles.	Dementia, apoplexy, aphasia, insomnia, poor memory, manic psychosis, epilepsy, hysteria; headache, vertigo, tinnitus; prolapse of rectum, prolapse of uterus, prolapse of stomach and kidney	Needle perpendicularly 0.5-0.8 *cun*. Moxibustion can be used for reinforcing Yang
GV29 *(Yintang)*	On the forehead, at the midpoint between the two medial ends of the eyebrow	Dementia, epilepsy, insomnia, poor memory; headache, dizziness; epistaxis, rhinorrhea; infantile convulsion, postpartum syncope due to blood loss.	Needle perpendicularly 0.3–0.5 *cun*
EX-HN22 *(Anmian)*	On the napex, at the midpoint between TE17 and GB20.	Insomnia, headache, Dizziness; palpitation; Manic psychosis	Needle perpendicularly 0.8-1.2 *cun.* Moxibustion can be used for reinforcing Yang.
SP6 *(Sanyinjiao)*	Behind the medial tibia, 3 *cun* above the tip of the medial malleolus	Helps in gynecological disorders	Needle perpendicularly 0.5–1.0 *cun*

Figures

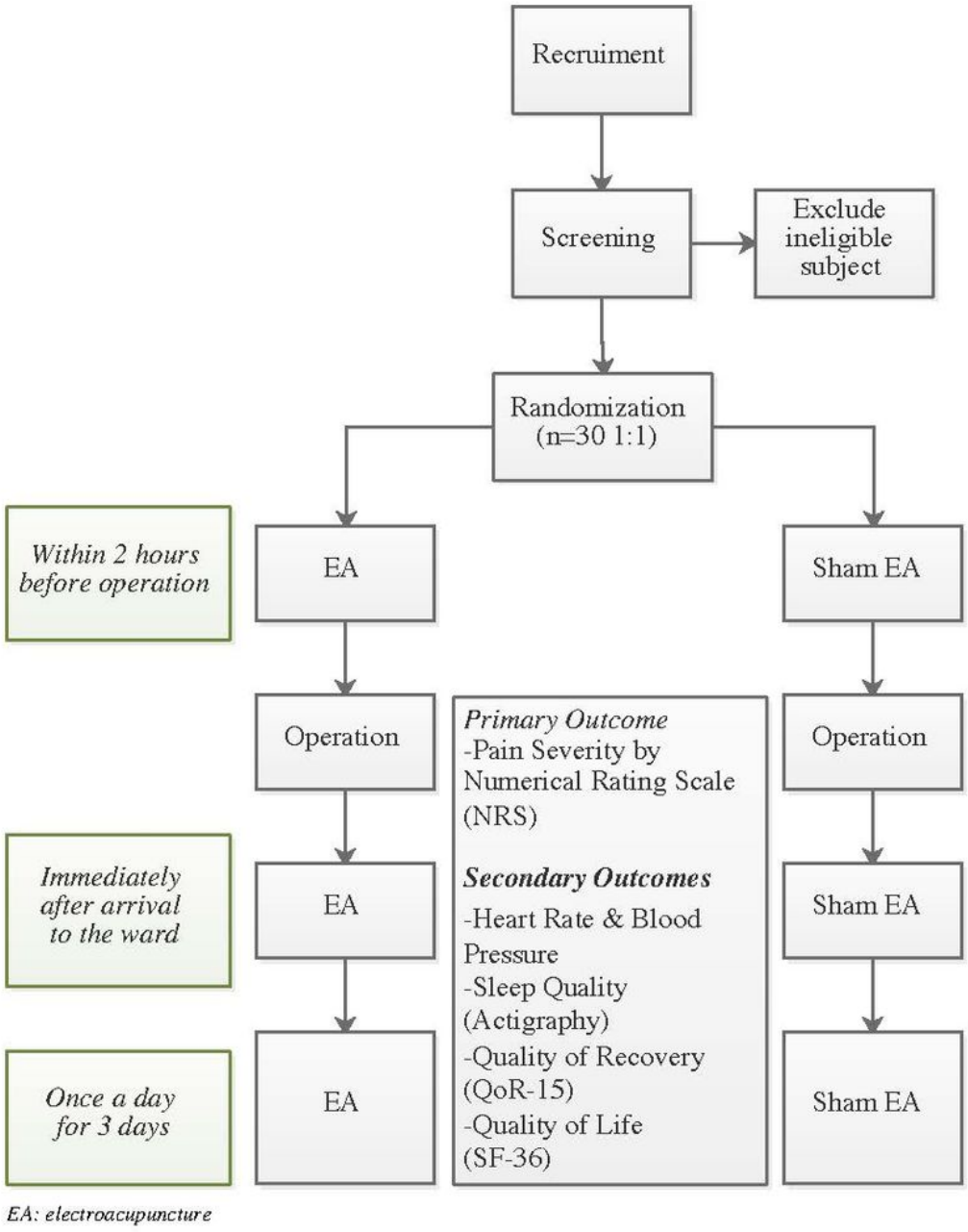

Figure 1. Flowchart of this study

Figure 1

Flowchart of this study

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