Version Date: (Version 2, 06/06/2024)

Subject Consent Form

This document is a formal Subject Consent Form for participation in a clinical study.

Institution: Buddhist Tzu Chi Medical Foundation Hualien Tzu Chi Hospital

Date of Version: June 6, 2024

Document Version: V2

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Valid only with the committee seal affixed

Subject Consent Form

Revised at the Institutional Review Board Meeting on November 28, 2023

Project Title

Chinese: 探討經胸腔部位手術之病患接受經皮穴位電刺激後對術後疼痛、心率變異、經絡能量、生活品質及血液發炎指標的影響。

English: Exploring the Impact of Transcutaneous Electrical Acupoint Stimulation Therapy on Reducing the Postoperative Pain, Heart Rate Variability, Meridian Energy, Quality of Life, and Blood Inflammatory Markers in the Patients After Thoracic Surgery.

Conducting Institution: Buddhist Tzu Chi Medical Foundation Hualien Tzu Chi Hospital

Funding Source: Hualien Tzu Chi Hospital

Principal Investigator: Chun-Ya Lin

Department: Nursing Department, Hualien Tzu Chi Hospital

Phone: 0911-292712

Co-Investigator: Pi-Sung Chang

Department: Thoracic Surgery, Hualien Tzu Chi Hospital

Phone: 03-8561825#11230

Co-Investigator: Chun-Hou Huang

Department: Department of Nursing, Tzu Chi University

Phone: 03-8565301#2260

24-Hour Project Contact: Chun-Ya Lin

Phone: 0911-292712

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Subject Name: _____

Date of Birth: _____

You are invited to participate in this trial. This form provides you with relevant information about the trial. The principal investigator or their authorized personnel will explain the contents of the trial and answer any questions you may have. Please do not sign this consent form until your questions are satisfactorily answered. You do not have to decide immediately whether or not to participate in this trial. Please consider carefully before signing. You must sign the consent form to participate in this trial. If you agree to participate, this document will serve as your record of consent. Even after consenting, you may withdraw from the trial at any time without giving any reason.

I. Purpose of the Trial

The purpose of this trial is to evaluate the effectiveness of three pain management interventions on patients after thoracic surgery: conventional analgesic medication, transcutaneous electrical nerve stimulation (TENS), and transcutaneous electrical acupoint stimulation (TEAS). The goal is to assess differences and trends in terms of acute postoperative pain, heart rate variability, meridian energy, blood inflammatory markers, and quality of life.

II. Research Background / Trial Product Introduction

1. Research Background

Patients undergoing thoracic surgery often have chest tubes inserted to drain pleural effusion and monitor for complications such as postoperative bleeding or air leaks. The placement and removal of these tubes are a primary source of postoperative pain, along with surgical wound pain during the acute recovery phase. Poor pain control can delay recovery and significantly impact quality of life. Currently, morphine and non-steroidal anti-inflammatory drugs (NSAIDs) are commonly used. However, morphine may cause side effects such as nausea, vomiting, dizziness, and gastrointestinal discomfort, while NSAIDs may irritate the digestive system.

TENS has been widely used since the 1970s, based on the gate control theory of pain, and has demonstrated significant pain relief effects. This study combines TENS with traditional Chinese medicine theory by applying electrodes to specific acupoints to induce endogenous morphine production for pain relief. The study will investigate whether this combined method can reduce pain from chest tube removal and acute postoperative pain, alleviate sympathetic nervous tension, balance meridian energy, maintain or improve quality of life, and influence blood inflammatory markers.

2. Use of Medical Devices

TENS devices are commercially available in Taiwan. This study uses a mid-frequency stimulator (Model HT-66B) produced by Hong-Tai Medical Instruments Co., Ltd., approved by the Ministry of Health and Welfare (License No. 000637). The equipment is regularly maintained and calibrated by certified engineers to ensure participant safety.

III. Main Inclusion and Exclusion Criteria

The research staff will discuss with you the necessary conditions for participation. If you do not meet the eligibility criteria, you will not be able to participate in this trial.

(1) Inclusion Criteria (Eligibility to participate in this study):

1. Adults aged between 30 to 85 years who are undergoing thoracic surgery.

2. Patients who are conscious, capable of verbal communication, and willing to participate fully in the study procedures.

(2) Exclusion Criteria (You will not be eligible to participate in this study if any of the following apply):

1. History of epilepsy.

2. History of cardiac arrhythmias or currently taking anti-arrhythmic medication.

3. Patients currently using a pacemaker.

4. Patients currently experiencing acute infections, immunodeficiency, or are carriers of hepatitis B/C or have autoimmune diseases.

IV. Trial Methods and Procedure Description

The research process will last four days during your current hospital stay. A total of 114 participants are expected to be enrolled and randomly assigned to one of three groups using computer-generated numbers. Each participant has an equal chance of being assigned to any group. Measurements will be taken at the following time points: pre-surgery (T1), before bedtime on the day of surgery (T2), before bedtime on the first postoperative day (T3), and after chest tube removal on the second postoperative day (T4).

Measurements include the Numeric Pain Rating Scale, heart rate variability, meridian energy, the 12-item Short Form Health Survey (SF-12), and the Hospital Anxiety and Depression Scale. Blood test data will be collected from routine lab results in the electronic medical records.

Group A: Routine treatment group.

Group B: TENS group — two electrode pads will be placed on the same-side back of the surgical site.

Group C: TEAS group — two electrode pads will be placed on the same-side back of the surgical site, and two additional pads will be placed on the acupoints Hegu (LI4) and Neiguan (PC6) of the same-side arm.

Intervention time: Both Group B and Group C will receive stimulation for 30 minutes.

Measurement time: Measurements will be taken after the intervention and will take approximately 10–15 minutes.

V. Potential Risks or Side Effects and Management Measures

During your participation, if you feel any discomfort, please immediately inform the researcher.

• Before treatment, you will first feel the electrical stimulation to test your sensitivity. If it causes itching or sensitivity and you cannot tolerate it, treatment will be stopped immediately. If discomfort causes you to withdraw from the study, your decision will be respected.

• Before treatment, the electrode patches will be tested on your skin to check for any allergic reaction to the gel. If redness or itching occurs, the patches will be removed and the skin cleaned. You may withdraw if discomfort arises.

• If the measurement procedure takes too long and causes discomfort or impatience, you may choose to withdraw, and your decision will be respected.

VI. Alternative Treatments and Explanation

To relieve postoperative pain under conventional care, oral analgesics are given regularly. If pain persists, morphine injections or NSAIDs may be used. Participation in this study is not mandatory for pain relief. You may choose other available treatment options, including self-paid patient-controlled analgesia (PCA).

VII. Expected Benefits

Since morphine may cause postoperative nausea and vomiting, and NSAIDs may cause gastrointestinal discomfort, this study explores whether TENS and TEAS can effectively alleviate acute postoperative pain and reduce the need for such medications. While TENS is widely used in Western medicine, combining it with traditional Chinese acupoint theory has gained attention. This study investigates whether TEAS, in addition to conventional analgesics, can provide more effective postoperative pain relief. However, participation in this trial does not guarantee effectiveness for pain relief.

VIII. Contraindications, Restrictions, and Obligations for Subjects During the Trial

To ensure your safety during the trial, please follow these requirements:

• If you develop an acute infection during the study, you will be withdrawn for safety.

• Please provide accurate medical history and information about your current condition.

• Report any discomfort to the principal investigator.

• Do not take other medications, including over-the-counter drugs, herbal medicine, or supplements, without discussing with the investigator.

• If you have any questions, feel free to consult the investigator directly.

IX. Confidentiality of Subject Personal Data

All records containing identifiable personal information will be treated confidentially. Your identity will be replaced by a research code, which will not reveal your name, national ID number, or address. Data will be stored using secure information technology and kept in a restricted access office.

If the results of this study are published, your identity will remain confidential. By signing the consent form, you agree to allow authorized personnel, including monitors, auditors, the Institutional Review Board (IRB), and regulatory authorities to review your personal and research data to ensure compliance with relevant laws and regulations. These individuals are bound to uphold confidentiality.

X. Withdrawal, Suspension/Termination of Trial and Handling of Personal Data and Specimens

You are free to decide whether or not to participate in this trial. During the trial, you may withdraw your consent at any time without providing a reason. This will not affect your rights or cause any disadvantage.

If new important information arises during the study that may affect your willingness to continue, you will be informed and may reassess your decision to participate. Your rights will not be affected by choosing to withdraw.

For your safety, the principal investigator may also decide to withdraw you from the trial if deemed unsuitable. The investigator may suspend or terminate the trial as necessary.

XI. Compensation and Insurance

This trial may involve risks. To ensure your protection in the event of adverse effects, please note:

(1) If you experience any adverse reactions or harm resulting from this trial, necessary assistance will be provided by the hospital.

(2) Beyond this assistance, the study does not provide any additional form of compensation. If you are unwilling to accept these risks, please do not participate.

(3) You will not waive any legal rights by signing this consent form.

(4) This study does not carry liability insurance.

XII. Storage and Reuse of Human Specimens or Personal Data (Research Materials)

The research materials you provide will be used only for this study and stored in a locked cabinet in the office of the surgical intensive care unit nurse practitioner, Chun-Ya Lin, at Hualien Tzu Chi Hospital. The materials will be retained until August 25, 2027, and destroyed thereafter according to regulations.

If you have concerns about the use of your research materials or wish to request their destruction, please contact us (Contact: Chun-Ya Lin; Department: Surgical ICU; Phone: 0911-292712). You may also contact the IRB at Hualien Tzu Chi Hospital (Phone: 03-8561825 ext. 12124) to assist with any related disputes.

XIII. Subject Rights

(1) Participation Subsidy:

You will receive a NT$100 PX Mart voucher after each of the four measurements: (T1) before surgery, (T2) on the day of surgery, (T3) the day after surgery, and (T4) the second day after surgery. A total of NT$400 in vouchers will be provided.

(2) You will not bear any costs for participating in this study.

(3) Any significant findings during the trial that may affect your willingness to continue will be shared with you promptly.

(4) This study has been reviewed and approved by the IRB of Hualien Tzu Chi Hospital. The review includes assessment of risks and benefits, participant rights, and data protection. If you have questions or concerns, contact the IRB at 03-8561825 ext. 12124.

(5) If you have any questions during the study, please feel free to contact Chun-Ya Lin, the nurse practitioner of the Surgical ICU. (24-hour contact number: 0911-292712)

(6) This consent form is provided in duplicate. One signed copy will be given to you after the investigator or authorized person explains the study details and answers your questions.

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I confirm that I have received a copy of this consent form.

Signature: _____ Date: _____ Year ___ Month ___ Day

XIV. Potential Commercial Benefits and Usage Agreement

This trial is not expected to generate any patents or commercial benefits.

XV. Consent Form Signing Instructions

1. The principal investigator or their authorized personnel must explain the study and answer all subject questions before signing. The investigator signs and dates first, followed by the subject or their representative after consideration.

2. Signature Requirements for Legal Representatives/Authorized Individuals/Guardians/Assistants:

• For legally incompetent individuals (under age 7 or declared under guardianship): Consent is given by a legal guardian.

• For individuals with limited capacity (ages 7 and above or under court-appointed assistance due to mental incapacity): Consent must be given by both the subject and their legal representative or assistant.

• For individuals unable to communicate due to mental or cognitive impairment: Consent is provided by an authorized person, such as a spouse or cohabiting relative.

• For research involving fetuses: Consent must be given by the mother.

• For deceased individuals: Written consent must be obtained from the closest relative or given prior to death.

3. When a Witness is Required:

• If the subject or legal representative cannot read, a witness must be present during all discussions. The witness must read the consent form and all other provided documents and confirm the subject fully understands the content.

• The subject/legal representative must still sign and date the consent form (or provide a fingerprint if unable to sign).

• The witness must confirm the consent was given voluntarily and sign and date the form.

• Research personnel may not act as witnesses.

• If a mark or symbol is used instead of a signature, it must be certified by two individuals to carry the same legal effect.

4. Order of Authorized Persons to Provide Consent:

• In studies involving special populations, if a participant is not capable of giving consent, authorized individuals may provide it in the following order:

1. Spouse
2. Adult children
3. Parents
4. Siblings
5. Grandparents

If there is disagreement, priority is determined by order, degree of kinship, cohabitation status, and age.

XVI. Signatures

(1) The principal investigator, co-investigator, or authorized personnel has explained the nature, purpose, and risks/benefits of this study.

Explanation provided by (check one): □ Principal Investigator □ Co-/Associate Investigator □ Research Personnel

Printed Name and Signature: _____ Date: _____ Year ___ Month ___ Day

(2) I have fully understood the methods and potential risks/benefits after explanation, and I agree to participate in this study. I will retain a copy of this consent form.

Subject Signature: _____ Date: _____ Year ___ Month ___ Day

Contact Phone Number: _____

(3) Legal Representative / Authorized Person / Guardian / Assistant

Signature: _____ Date: _____ Year ___ Month ___ Day

Relationship to Subject (circle one): Spouse / Father / Mother / Son / Daughter / Other: _____

Contact Phone Number: _____

(4) Witness

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Witness 1 Signature: _____ Date: _____ Year ___ Month ___ Day

Contact Phone Number: _____

Witness 2 Signature: _____ Date: _____ Year ___ Month ___ Day

Contact Phone Number: _____