ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: October 19, 2020

ClinicalTrials.gov ID: [Not yet assigned]

Study Identification

Unique Protocol ID:	CMUH109-REC2-131
Brief Title:	The Effectiveness of Acupressure for Managing Postoperative Pain and Anxiety in Patients With Thoracoscopic Surgery.
Official Title:	Professor, School of Nursing, China Medical University Hospital, Principal Investigator.
Secondary IDs:	

Study Status

Record Verification:	October 2020
Overall Status:	Recruiting
Study Start:	September 20, 2020 [Actual]
Primary Completion:	August 2021 [Anticipated]
Study Completion:	September 2021 [Anticipated]

Sponsor/Collaborators

Sponsor:	Wei-Fen Ma
Responsible Party:	Sponsor-Investigator Investigator: Wei-Fen Ma [lhdaisy] Official Title: Professor, School of Nursing Affiliation: China Medical University Hospital
Collaborators:	China Medical University Hospital

Oversight

U.S. FDA-regulated Drug:	No
U.S. FDA-regulated Device:	No
U.S. FDA IND/IDE:	No
Human Subjects Review:	Board Status: Approved Approval Number: CMUH109-REC2-131 Board Name: Research Ethics Committee China Medical University and Hospital, Taichung, Taiwan Board Affiliation: China Medical University and Hospital Phone: 886-4-22052121 Email: Address:

2 Yude Road, Taichung, 40447, Taiwan

Data Monitoring: No

FDA Regulated Intervention: No

Study Description

Brief Summary: The purpose of this study is to explore the effectiveness of acupressure for managing postoperative pain, anxiety, analgesia consumption, early ambulation, and comfort in patients with thoracoscopic surgery.

Detailed Description: Thoracoscopic surgery is the surgical used to removal of a section or a segment of a lung lobe. One US national survey reported that 80% of patients undergoing pulmonary surgery experienced acute pain. 75-86% of these patients pointed out that experienced moderate, severe, or extreme pain, especially, on the 1st day after thoracoscopic surgery. However, inappropriate pain management after surgery is associated with limited the healing process, increased workload of heart, prolonged pulmonary rehabilitation, and increased medical costs, and can be a prediction of developing chronic pain. Acupressure is a nonpharmacological treatment for the management of postoperative pain. Recent studies have found that the application of acupressure is effective in decreasing operative pain intensity, morphine related side effects, and opioid consumptions after surgery. However, there was no further research about the role of acupressure applied to thoracoscopic surgery.

Conditions

Conditions: Lung Diseases

Keywords: acupressure
thoracoscopic surgery
acute pain
anxiety
comfort

Study Design

Study Type: Interventional

Primary Purpose: Supportive Care

Study Phase: N/A

Interventional Study Model: Parallel Assignment

Number of Arms: 2

Masking: Single (Participant)

Allocation: Randomized

Enrollment: 200 [Anticipated]

Arms and Interventions

Arms	Assigned Interventions
Experimental: acupressure After recruitment, participants will be randomized to receive acupressure or control group. In the	acupressure The acupressure involves the " Vaccaria Semen" within skin-colored adhesive tape that placed on

Arms	Assigned Interventions
acupressure group, participants will receive acupressure treatment.	the "Neiguan" and "Shenmen" acupoints as an intervention measure. Continue to massage the acupoints with fingertips for 10 minutes, 3 times per day (8 and 12 in the morning, and 4 in the afternoon) . The adhesive tape will be retained in situ for 2 days.
No Intervention: routine care After recruitment, participants will be randomized to receive acupressure or control group. In the control group, participants will receive routine care, including routine pain control.	

Outcome Measures

Primary Outcome Measure:

1. Pain:Changes from baseline pain scale at post-operative day 2, after intervention.
   as assessed by Visual Analogue Scale-Pain (VAS-P). The VAS#P scale is comprised of a horizontal line 100mm long with the indication “no pain” to the left and “worst possible pain” to the right. possible scores varied between 0–100. A higher scores mean a worse outcome.

   [Time Frame: Measure at before operation day, 7 post meridiem (PM), before operation; post-operative day1, 8 ante meridiem (AM), before intervention; post-operative day 1, 5 PM, after intervention; and post-operative day 2, 5 PM, after intervention]

Secondary Outcome Measure:

2. Anxiety
   as assessed by Visual Analogue Scale-Anxiety(VAS-A). The VAS#A scale is comprised of a horizontal line 100mm long with the indication “no anxiety” to the left and “worst possible anxiety” to the right. possible scores varied between 0–100. A higher scores mean a worse outcome.

   [Time Frame: Measure at before operation day, 7 post meridiem (PM), before operation; post-operative day1, 9 ante meridiem (AM), before intervention; post-operative day 1, 5 PM, after intervention; and post-operative day 2, 5 PM, after intervention.]

3. Anxiety
   as assessed by State-Trait Anxiety Inventory (STAI) Y form (STAI-Y1). It is 20 questions, which were rated from 1–4. Possible scores varied between 20–80. A STAI-Y1 score>40 as evidence of a state of anxiety.

   [Time Frame: Time Frame: Measure at before operation day, 7 post meridiem (PM), before operation; post-operative day1, 8 ante meridiem (AM), before intervention; and post-operative day 2, post meridiem (PM), after intervention.]

Other Pre-specified Outcome Measures:

4. Analgesia Consumption
   Injection time of morphine and ketorolac would be recorded.

   [Time Frame: during the whole admission, an average of 4 day.]

5. Comfort
   as assessed by Shortened General Comfort Questionnaire

   [Time Frame: Measure at before operation day,7 post meridiem (PM), before operation; post-operative day 1, 8 ante meridiem (AM), before intervention; and post-operative day 2, 5pm, after intervention]

6. Heart rate variability
   as assessed by Nexus-10, wireless Biofeedback/Neurofeedback system

   [Time Frame: Measure at before operation day, 7 post meridiem (PM), before operation; post-operative day1, 8 ante meridiem (PM), before intervention; post-operative day 1, 5 post meridiem (PM), after intervention; and post-operative day 2, 5 PM, after intervention.]

7. Early ambulation
   The first ambulation time: act to walk with or without any kind of assistant after operation.

[Time Frame: The first ambulation time after operation would be recorded, assessed up to 7 days.]

Eligibility

Minimum Age: 20 Years

Maximum Age:

Sex: All

Gender Based:

Accepts Healthy Volunteers: Yes

Criteria: Inclusion Criteria:

- pulmonary lung disease and will be scheduled to undergo a thoracoscopic wedge resection, segmentectomy, or lobectomy.
- American Society of Anesthesiologist physical status of Classes I–II,
- both forearms without missing limbs or arteriovenous fistula
- ability to communicate in Taiwanese or Chinese, and
- agreement to participate in this study.

Exclusion Criteria:

- diagnosed as malignant neoplasm with lung meta,
- Had a stroke or peripheral vascular disease
- Platelet count less than 20 x 10^3/mm^3
- Using the patient controlled analgesia, and
- any known mental illness or memory dysfunction.

Contacts/Locations

Central Contact Person: Wei-Fen Ma, Ph.D
Telephone: 04-22053366 Ext. 7107
Email: lhdaisy@mail.cmu.edu.tw

Central Contact Backup: Wei-Fen Ma, Ph.D

Study Officials: Wei-Fen Ma, Ph.D
Study Principal Investigator
China Medical University, China

Locations: **Taiwan**
China Medical University
[Recruiting]
Taichung, Taiwan, 40447
Contact: Wei-Fen Ma, PHD 04-22053366 Ext. 7107
lhdaisy@mail.cmu.edu.tw
Contact: Wei-Fen Ma, PHD 04-22053366 Ext. 7107 lhdaisy@gmail.com
Principal Investigator: Wei-Fen Ma, Ph.D
Sub-Investigator: Hsing-Chi Hsu, MSc

IPDSharing

Plan to Share IPD: No

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Citations: **[Study Results]** Abouarab AA, Rahouma M, Kamel M, Ghaly G, Mohamed A. Single Versus Multi-Incisional Video-Assisted Thoracic Surgery: A Systematic Review and Meta-analysis. J Laparoendosc Adv Surg Tech A. 2018 Feb;28(2):174-185. doi: 10.1089/lap.2017.0446. Epub 2017 Nov 6. Review. PubMed 29106318

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Links: URL: https://www.asahq.org/standards-and-guidelines/asa-physical-status-classification-system
Description American Society of Anesthesiologists Physical Status Classification System.

Available IPD/Information:

Cover page

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Title: The Effectiveness of Acupressure for Managing Postoperative Pain and Anxiety in Patients With Thoracoscopic Surgery

Statistical Analysis Plan

SPSS statistical software was used for data analysis, independent t test and chi-square test were used for descriptive analysis. A mixed model with repeated analysis was used to examine the effect of acupressure on pain, anxiety, and comfort. Regression analysis was to explore the influences of pain, anxiety, and comfort for study patients with thoracoscopic Surgery.

Primary Completion Date

The patient experienced moderate pain and anxiety after thoracoscopic surgery. There was no significant difference in demographic characteristics between the two groups before they received surgery. The experimental group, compared with the control group, pain intensity (p<0.01) and anxiety score (p<0.05) were statistically significant lower on day 1 and day 2 after intervention. The STAI-Y1 score (F=2.514, p=.086) and comfort level (F=2.953, p=.057) were no significant differences after intervention between two groups. The longer intervention, the significantly decreased pain intensity (p<0.05) for surgical procedures with lighter pain perception.