STATISTICAL ANALYSIS PLAN

Effect of Transcutaneous Electrical Nerve Stimulation and Acupuncture-related Stimulation on Postoperative Pain and Recovery Following Video-Assisted Thoracoscopic Surgery

Randomized Controlled Trial
ClinicalTrials.gov Identifier: NCT Number Pending
Version: 2.0
Date: October 19, 2025

Principal Investigator:
Lin, Chun-Ya RN, MSN
Graduate Student, Department of Nursing, Tzu Chi University
Affiliated Unit: Department of Surgical Intensive Care, Tzu Chi Hospital

IRB Approval No.: IRB113-050-B
Sponsor / Institution: Tzu Chi Hospital and Tzu Chi University
Document Type: Statistical Analysis Plan (PDF/A)

1. Study Overview

This randomized controlled trial investigates the analgesic and physiological effects of Transcutaneous Electrical Nerve Stimulation (TENS) and TENS combined with acupuncture-related stimulation (TENS+TANS) on postoperative pain management and recovery among patients undergoing Video-Assisted Thoracoscopic Surgery (VATS). Participants are randomly assigned into three groups: Control (standard care), TENS, and TENS+TANS, with repeated assessments at preoperative (T0), immediate postoperative (T1), and postoperative day 3 (T2).

2. Objectives and Hypotheses

Primary Objective: To evaluate whether TENS or TENS+TANS significantly reduces postoperative pain intensity compared to standard care following VATS.

Secondary Objectives: To assess the effects of these interventions on emotional status (HADS), quality of life (SF-12), inflammatory indices (e.g., NLR, LMR), and postoperation complication.

Hypotheses:

H1: TENS and TENS+TANS will result in lower NRS pain scores over time compared to Control.

H2: The TENS+TANS group will demonstrate greater improvements , emotional outcomes, and recovery parameters.

3. Study Design and Intervention Groups

A total of approximately 94 participants will be recruited and randomly allocated to one of three groups using a computer-generated randomization table. Interventions will be applied postoperatively according to group assignment. Data will be collected at three time points (T0, T1, T2) for repeated-measures analysis.

Groups:

- Control: Standard postoperative care only.
- TENS: Conventional TENS applied according to thoracic pain dermatome.
- TENS+TANS: TENS combined with acupuncture-related electrical stimulation following meridian theory.

4. Outcome Measures

Primary Outcome:

- Numeric Rating Scale (NRS) pain intensity scores at rest and during activity.

Secondary Outcomes:

- SF-12 (PCS, MCS)
- Inflammatory indices: NLR, LMR
- HADS (Anxiety, Depression)
- Drainage volume, blood loss, operation type, and tube type

5. Statistical Methods

- All analyses will be conducted using IBM SPSS Statistics 25 (Armonk, NY, USA).
- Descriptive Statistics: Mean ± SD or median (IQR) for continuous variables; frequencies and percentages for categorical variables.
- Baseline Comparison: One-way ANOVA or Kruskal–Wallis test for continuous variables; Chi-square or Fisher's exact test for categorical variables.
- Primary Analysis: Repeated-measures ANOVA to test for within-subject effects (time), between-subject effects (group), and time × group interaction. Greenhouse–Geisser correction will be applied if sphericity is violated. Partial eta-squared (η^2p) will be reported as effect size.
- Post-hoc Analysis: Bonferroni-adjusted pairwise comparisons for significant main or interaction effects; Cohen's d will quantify between-group effect sizes.
- Secondary Analysis: Logistic regression to identify predictors of moderate-to-severe pain (NRS $\geq$ 4), including covariates such as age, sex, operation type, and drainage volume. Model performance will be assessed using Hosmer–Lemeshow goodness-of-fit and AUC of ROC curve.
- Sensitivity Analysis: Penalized (Firth) logistic regression and bootstrap resampling (1,000 iterations).
- Significance Level: Two-tailed $p < 0.05$.

6. Sample Size Calculation

Based on G*Power 3.1 calculations for a repeated-measures ANOVA (3 groups × 3 measurements), with medium effect size $f = 0.25$, $\alpha = 0.05$, and power = 0.80, a total of 84 participants are required. To account for 10% potential attrition, 94 participants will be recruited.

7. Handling of Missing Data

Missing data will be analyzed for randomness using Little's MCAR test. If data are missing at random, multiple imputation or expectation-maximization methods will be used. Sensitivity analyses will compare results before and after imputation.

8. Software and Significance Level

All statistical analyses will be performed using IBM SPSS 25 and verified in R 4.3.2 when applicable.

Statistical significance will be set at $p < 0.05$ (two-tailed). Effect sizes will follow Cohen's conventions (small $d = 0.2$, medium = 0.5, large = 0.8).

9. Amendments and Version Control

This Statistical Analysis Plan (Version 2.0, dated October 19, 2025) was prepared prior to database lock and unblinding. Any amendments will be documented with justification and dated accordingly.