

Study Protocol

Official Title: Clinical Characteristics and Outcomes of Non-Indicated Staged Laparotomies in Abdominal Trauma Patients: A Single-Center Retrospective Study

NCT Number: [Pending]

Document Date: 2025-08-03

Principal Investigator: Chien Wu, M.D.

Affiliation: Department of Surgery, Far Eastern Memorial Hospital

1. Study Overview

This retrospective observational study aims to investigate the clinical characteristics and outcomes of abdominal trauma patients who received staged laparotomies without meeting conventional indications. The study will analyze differences in patient outcomes, risk factors, and the potential implications of deviating from guideline-based indications.

2. Study Dates

Start Date: 2013-01-01

End Date: 2024-12-31

3. Study Population

Patients who underwent exploratory laparotomy for abdominal trauma at Far Eastern Memorial Hospital between January 1, 2013, and December 31, 2024.

4. Study Design

This is a single-center, retrospective observational cohort study. Patients will be grouped by surgical approach (single vs. staged laparotomy) and whether the initial operation met staged surgery criteria.

5. Objectives

To assess the frequency, clinical characteristics, and outcomes associated with non-indicated staged laparotomies.

6. Outcomes

Primary Outcome:

- All-cause mortality occurring no earlier than 24 hours after the most recent surgical intervention.

[Time Frame: From enrollment to the end of treatment at 6 months]

Secondary Outcomes:

- Postoperative complications including ileus, infection, poor wound healing, and incisional hernia.

[Time Frame: through study completion, an average of 1 year]

Statistical Analysis Plan

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1. Statistical Analysis Overview

This document outlines the statistical methods used to analyze clinical and outcome differences among patients who received indicated vs. non-indicated staged laparotomies.

2. Primary Analysis

The primary analysis will evaluate all-cause mortality occurring after surgical intervention using logistic regression models.

3. Secondary Analyses

Secondary outcomes including complications (e.g., ileus, infection) will be analyzed using univariate and multivariate logistic regression.

4. Statistical Methods

- Mann-Whitney U test for continuous variables
- Logistic regression for binary outcomes
- Propensity score matching to reduce confounding between comparison groups

5. Software

Statistical analyses will be performed using STATA version XX (replace with actual version used).