Study Protocol and Statistical Analysis Plan

Official Title:
Evaluation of the Efficacy of Laser Acupuncture on Uremic Pruritus

NCT Number: NCT06875115
Unique Protocol ID: B11301036
Document Date: 2025-12-14

This document contains the complete study protocol and the statistical analysis plan (SAP) for submission to ClinicalTrials.gov.

1. Study Objectives

The primary objective of this study is to evaluate the efficacy of laser acupuncture in reducing uremic pruritus in patients undergoing hemodialysis.
Secondary objectives include assessment of symptom severity, quality of life, and treatment safety.

2. Study Design

This is a prospective, randomized, controlled clinical study. Eligible participants will be allocated to intervention or control groups according to the study protocol. The study duration and assessment schedule are predefined.

3. Participants

Inclusion criteria include adult patients undergoing maintenance hemodialysis with clinically significant uremic pruritus.
Exclusion criteria include severe comorbid conditions or contraindications to laser acupuncture.

4. Interventions

Participants in the intervention group will receive laser acupuncture at predefined acupoints according to a standardized protocol.
The control group will receive usual care or sham treatment as specified.

5. Outcome Measures

The **primary outcome** is change in pruritus severity measured by validated scales.
Secondary outcomes include quality-of-life measures and adverse events.

6. Statistical Analysis Plan (SAP)

6.1 Analysis Populations

All randomized participants will be included in the intention-to-treat (ITT) analysis. A per-protocol analysis may be conducted as a secondary analysis.

6.2 Primary Outcome Analysis

The primary outcome will be analyzed using appropriate statistical tests based on data distribution. Between-group comparisons will be performed to evaluate treatment effects.

6.3 Secondary Outcome Analyses

Secondary outcomes will be analyzed using suitable parametric or non-parametric methods. Repeated measures may be analyzed using appropriate models.

6.4 Handling of Missing Data

Missing data will be handled using appropriate statistical methods, such as multiple imputation or last observation carried forward, depending on the nature and extent of missingness.

6.5 Significance Level and Statistical Software

All statistical tests will be two-sided with a significance level of 0.05. Statistical analyses will be conducted using standard statistical software.

7. Ethical Considerations

The study will be conducted in accordance with ethical principles and has received approval from the appropriate institutional review board.