

Cover page

Official title: Effectiveness of Electroacupuncture and Thread-Embedding Acupuncture in Patients With Knee Osteoarthritis: A Randomized, Assessor-Blinded, Parallel-Group Controlled Trial

NCT ID not yet assigned

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Statistical Analysis Plan

Data will be entered and managed using Microsoft Excel 365 and analyzed using R version 4.4.2. Analyses will be conducted according to both the intention-to-treat and per-protocol principles, with intention-to-treat as the primary analytic approach.

Baseline demographic and clinical characteristics will be summarized by treatment group. Continuous variables will be presented as mean, standard deviation, and 95 percent confidence interval, or as appropriate according to distribution. Between-group baseline comparisons will use independent-sample t tests or Wilcoxon rank-sum tests. Categorical variables will be presented as frequencies and percentages and compared using the chi-square test or Fisher's exact test.

For the primary outcome and repeated secondary continuous outcomes, differences over time, between groups, and group-by-time interactions will be analyzed using repeated-measures two-factor analysis of variance. For variables measured before and after treatment, within-group changes will be calculated and between-group comparisons will be performed using t tests for normally distributed data or Mann–Whitney tests for non-normally distributed data. Adverse events will be summarized descriptively, and between-group comparisons will use the chi-square test when appropriate. The statistical significance level will be set at 0.05.