

Efficacy of Laser Debridement on Pain and Bacterial Load in Chronic Wounds (NCT03182582)

Statistical Analysis Plan

February 6, 2018

Geoffrey C. Gurtner, Principal Investigator
Stanford University
Stanford, California 94305

Methods:

This is a prospective, randomized, controlled, crossover clinical trial, entailing two groups: 1) one group receiving a single laser debridement session first, followed by a single sharp debridement session one week later; 2) the other group receiving a single sharp debridement session first, followed by a single laser debridement session one week later. Analysis variables include pain during debridement, pre- and post-debridement wound sizes, pre- and post-debridement bacterial loads, and patient preference.

Statistical Analysis:

The a priori power analysis presumes a 50% reduction in patient-reported pain. A sample size of 22 patients would be required to achieve 80% power, using a two-tailed test with $\alpha = 0.05$. Descriptive analyses include means (standard deviation). A paired t-test was planned to evaluate continuous data, and the 3x2 Fisher's exact test was planned to analyze categorical data. For all data analyses performed in the study, $p < 0.05$ is considered statistically significant.