

TITLE: STUDY TO EVALUATE THE SAFETY, EFFICACY AND TOLERANCE OF INTENSE THERAPEUTIC ULTRASOUND (ITU) FOR THE TREATMENT OF LATERAL EPICONDYLITIS

PROTOCOL NO. and WIRB NO: 20150654

DATE: March 2, 2015

Principal Investigator: John A. Kearney, Jr. MD

The More Foundation
18444 N 25th Ave
Suite 110
Phoenix, AZ 85023

Sponsor: Guided Therapy Systems

33 S. Sycamore
Mesa, AZ 85202-1150

Statistical Analysis Plan:

Statistical Methods

Pain Reduction:

Pain level for subjects at the region of interest was self-reported at pre-treatment, used as baseline, and again at each follow-up at 4, 8, 12, and 26 weeks following initial treatment. The pain scale subjects used to identify their level of pain was a 10-point pain scale, where 0 = no pain, 1 = slight pain, through 10 which equates to the patients' worst imaginable pain. The goal for all subjects was to reduce pain by at least 25%. For patients reporting an initial (baseline) score ranging 6-10, this reflects a VAS pain score reduction \geq a 2 point drop; for initial scores ranging 2-5, this reflects a VAS pain score reduction \geq a 1 point drop. Pain scores reported at follow-up timepoints were compared to baseline score for each subject to determine if the goal was met by dividing the difference in the follow-up and baseline pain score by the baseline pain score. The percentage of subjects that met the pain reduction goal was calculated at each timepoint for both groups by dividing the number of subjects that achieved the pain reduction goal at that timepoint by the total number of patients that gave a pain score for that timepoint.

Patient Rated Tennis Elbow Evaluation Score Reduction:

In addition to the 10-point VAS pain scale, patients self-reported answers to questions from the Patient Rated Tennis Elbow Evaluation (PRTEE) questionnaire, which has been standardized for use in research studies to evaluate patient's level of pain and function^[10]. Scores range from 0-100, with 0 indicating no pain and 100 indicating the worst pain imaginable in a variety of daily activities. Self-reported scores were taken at baseline and each follow-up timepoint. The average score for each timepoint were calculated, and follow-up averages were compared to baseline to calculate the percentage reduction in score.