Effectiveness of PACE and SOC Compared to SOC Alone for Diabetic Foot Ulcers: Clinical Trial Design

Purpose

Approximately 25% of diabetics will develop a DFU at an average cost of $4,595.00 to $28,691.00. Given this magnitude, DFU trials evaluating modalities must have robust designs for the unbiased evaluation of endpoints in order to affect global regulatory approvals and reimbursement.

Methods

Pulsed Acoustic Cellular Expression (PACE) Technology is a novel modality that is postulated to initiate a biological response at the cellular level stimulating the production of growth factors, promoting angiogenesis, cellular proliferation and regeneration. This trial is designed to determine the safety and efficacy of PACE along with SOC for the treatment of DFUs compared to sham-controlled applications with SOC.

Effectiveness will be assessed by comparing DFU closure in the active (PACE) and sham-control groups after 12 weeks. Other endpoints will include rate of closure, time to closure and pain scores. A blinded Investigator will review results while an unblinded clinician performs the treatment for a convincing double-blinded study. Further patient blinding will be assured using an active (PACE) and sham (placebo) apparatus that have identical treatment applicators such that the same audible sounds will be heard by patients receiving either active or sham treatment.

Results and Conclusions

Procedures and data collection to date have been without incident and study confidence has been maintained. This suggests a convincing double-blinded, sham-controlled study design that should prove valuable for the unbiased evaluation and, if positive, support global regulatory approvals and reimbursement.