Effectiveness of Pulsed Acoustic Cellular Expression (PACE) and Standard of Care Compared to Standard of Care Alone for Diabetic Foot Ulcers: Clinical Trial Design

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Purpose
Approximately 25% of people with diabetes will develop a Diabetic Foot Ulcer (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.

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 Standard of Care (SOC) for the treatment of DFU’s 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 subject 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 subjects receiving either active or sham treatment.

CLINICAL ENDPOINTS

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<thead>
<tr>
<th>Endpoint</th>
<th>Measurement</th>
<th>Timeframe</th>
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<tbody>
<tr>
<td>Rate of Closure</td>
<td>Measured by Percentage of Change (Volume Depth, and Perimeter)</td>
<td>12 Weeks Post Initial Application</td>
</tr>
<tr>
<td>Time of Closure</td>
<td>Measured in Days (Volume, Depth, and Perimeter)</td>
<td>12 Weeks Post Initial Application</td>
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<tr>
<td>Pain Score</td>
<td>Measured on a Visual Analog Scale (VAS)</td>
<td>24 Weeks Post Initial Application</td>
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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.