Efficacy and Safety of Poly-N-Acetyl-Glucosamine, Nanofiber-Derived Advanced Wound Healing Technology (pGlcNAC) for Treatment of Patients with Venous Leg Ulcers: A Randomized, Controlled, Investigator-Blinded Pilot Study

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Abstract

Background: Chronic venous leg ulcers (VLU) affect an estimated 2.5 million adults in the United States, with 600,000 new cases occurring annually. These wounds are associated with substantial morbidity and mortality, and annual treatment costs exceed $3 billion. The current standard of care includes cleaning, debridement, dressings, and compression therapy. Promising new therapies that promote healing include wound, monolayer elastic high-compression bandaging, leg elevation, and lower extremity exercise. When treated with the current standard of care, approximately 65% of patients achieve complete healing at 6 months.

Methods: This 2-week, single-center, investigator-blinded, parallel-group, controlled, pilot study included 60 patients (20 patients per group) randomized to receive standard care (pGlcNAC or standard care, alone) and 20 patients with hard-to-heal VLU standard care (pGlcNAC plus standard care) or to standard care (polyvinyl alcohol, blended daily; pGlcNAC alone or pGlcNAC plus standard care). Ulcers were demonstrated by ultrasound assessing for ulcers ≥ 1 cm in diameter and more than 2 mm in thickness. The primary endpoint was complete wound healing at 12 weeks among all patients with hard-to-heal VLU included in the analysis. Patients with no exposed ulcer surface were censored and were considered healed if all the criteria were achieved.

Results: Patients were evaluated every week using a modified Venous Ulcer Scale total score of 0-100. For patients receiving standard care plus every other day administration of pGlcNAC versus 45% of those receiving standard care alone (p=0.05). No significant treatment-related adverse events or reactions occurred during the study and no unexpected increased pain or edema.

Conclusions: This 2-week, single-center, investigator-blinded, parallel-group, controlled, pilot study included 60 patients with hard-to-heal VLU (standard care vs. pGlcNAC). The treatment was shown to be significantly effective in treating patients with hard-to-heal VLU. No additional adverse effects were noted.

References


Table 1: Baseline Sample Characteristics

<table>
<thead>
<tr>
<th>Group</th>
<th>Age, years (SD)</th>
<th>Sex, %</th>
<th>Diabetes, %</th>
<th>Strokes, %</th>
<th>Heart Failure, %</th>
<th>Arterial Disease, %</th>
<th>Baseline VLSU, mean (SD)</th>
<th>Baseline VLSU, median (SD)</th>
<th>Baseline VLSU, min-max</th>
<th>Baseline VLSU, SD</th>
<th>Baseline VLSU, IQR</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>69.4 (11.3)</td>
<td>70%</td>
<td>40%</td>
<td>40%</td>
<td>25%</td>
<td>45%</td>
<td>45.0% (13)</td>
<td>45.0% (13)</td>
<td>0-100</td>
<td>15.0%</td>
<td>10.0%</td>
</tr>
<tr>
<td>B</td>
<td>69.8 (11.5)</td>
<td>60%</td>
<td>50%</td>
<td>40%</td>
<td>20%</td>
<td>40%</td>
<td>45.0% (12)</td>
<td>45.0% (12)</td>
<td>0-100</td>
<td>15.0%</td>
<td>10.0%</td>
</tr>
</tbody>
</table>

Outcomes: Value

Table 2: Percentage of Patients Completely Healed at Week 20

<table>
<thead>
<tr>
<th>Group</th>
<th>Percent Complete Healed (pGlcNAC)</th>
<th>Percent Complete Healed (pGlcNAC+SCP)</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>46.5% (9)</td>
<td>66.4% (17)</td>
<td>0.05</td>
</tr>
<tr>
<td>B</td>
<td>46.0% (9)</td>
<td>66.5% (12)</td>
<td>0.05</td>
</tr>
</tbody>
</table>

*As shown in Table 2, only Group B (pGlcNAC applied every other day) had a significantly greater proportion of patients with completely healed wounds compared with standard care (p=0.05).

**Four patients developed severe infections that were determined to be unrelated to their wounds or study treatment. No significant treatment-related adverse events or reactions occurred during the study and no subjects experienced increased pain or change.

Disclosures

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