Efficacy and Safety of Collagenase Clostridium Histolyticum (CCH) in the Treatment of Proximal Interphalangeal (PIP) Joints in Dupuytren Contracture: Results of Four Phase 3 Clinical Trials

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OBJECTIVES

Analysis was undertaken to determine the efficacy and safety of Collagenase Clostridium Histolyticum (CCH) injections for the treatment of Dupuytren contracture of the proximal interphalangeal (PIP) joint.

METHODS

This was a retrospective analysis of four phase 3 clinical trials, CORD I/II ¹ ² and Joint I/II ³

• 506 subjects enrolled, 404 M, 102 F, mean age 62 years
• 644 PIP joints
• Clinical Success (0°-5° extension) was determined
• Clinical Improvement (≥ 50% contracture reduction) was determined
• Improvement in range of motion (ROM) was determined
• All measures were at 30 days after first and last CCH injections
• Per protocol, a maximum of 3 injections per cord were allowed, 30 days apart
• Adverse events (AEs) were assessed

RESULTS

Number of Injections (n=644 joints)

- Mean Baseline PIP Joint Contracture=47.7°
- Mean 1.6 Injections

Clinical Success and Clinical Improvement (n=644 joints)

- Clinical Success and Clinical Improvement after last injection were markedly higher in subjects with low (< 40°) baseline severity compared to high baseline severity (≥ 40°)
  - Low Severity Clinical Success = 51%
  - Low Severity Clinical Improvement= 68%
  - High Severity Clinical Success= 27%
  - High Severity Clinical Improvement= 55%
- Mean Change in Range of Motion increased:
  - from 51° at baseline to 71° after first injection and to 75° after last injection

CONCLUSIONS

• Collagenase Clostridium Histolyticum (CCH) injections for the treatment of PIP joints in Dupuytren Contracture are safe and effective
• Clinical outcomes were better in the low baseline severity group (<40°) compared to the high baseline severity group (≥ 40°) suggesting earlier intervention may be beneficial

AEs ≤ 30 days After Each Injection

<table>
<thead>
<tr>
<th>Adverse Event</th>
<th>Incident Count</th>
<th>Total Injections (n=1165)</th>
<th>Percent of Total Injections</th>
</tr>
</thead>
<tbody>
<tr>
<td>Edema peripheral</td>
<td>679</td>
<td>58.3%</td>
<td></td>
</tr>
<tr>
<td>Contusion</td>
<td>443</td>
<td>38.0%</td>
<td></td>
</tr>
<tr>
<td>Injection site hemorrhage</td>
<td>268</td>
<td>23.0%</td>
<td></td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>261</td>
<td>22.4%</td>
<td></td>
</tr>
<tr>
<td>Injection site pain</td>
<td>243</td>
<td>20.9%</td>
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</tr>
<tr>
<td>Injection site swelling</td>
<td>189</td>
<td>16.2%</td>
<td></td>
</tr>
<tr>
<td>Tendon Rupture (5th finger)</td>
<td>2</td>
<td>0.0017%</td>
<td></td>
</tr>
</tbody>
</table>