Safety and Effectiveness of Collagenase Clostridium Histolyticum (CCH) in the Treatment of Peyronie's Disease Using a Modified Protocol

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Disclosures

• Amr Abdel Raheem: clinical investigator for Auxilium Pharmaceuticals, Inc. and consultant for Sobi.

• David J Ralph: clinical investigator for Auxilium Pharmaceuticals, Inc. and consultant for American Medical Systems, Inc., Coloplast Corp, and Auxilium Pharmaceuticals, Inc

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Introduction

Collagenase clostridium histolyticum (CCH) (Xiapex®) is the only licensed product for the treatment of PD.

The clinical safety and efficacy of CCH in subjects with PD was shown in two large phase 3 randomized, double-blind, placebo-controlled studies; IMPRESS I & II.
Objective

- The aim of this study is to evaluate the efficacy and safety of CCH in the treatment of PD using a new modified treatment protocol which aims at reducing the number of injections needed and reducing patient visits, thus reducing the cost and duration of treatment.
**New Protocol**

CCH Treatment Cycle repeated after 4 weeks for ≤3 treatment cycles

- A single CCH injection 0.9mg
- 24-72 hours
- Patient Home gentle straightening of erect penis
- + Penile stretching
- + Vacuum pump
- No investigator modelling

No visits: 4 (including assessments)
Duration of treatment: 12 weeks

**Trial Protocol**

CCH Treatment Cycle repeated after 6 weeks for ≤4 treatment cycles

- 1st CCH Injection 0.58mg
- 2nd CCH Injection 0.58mg
- 24-72 hours
- Investigator plaque modeling

No visits: 14
Duration of treatment: 24 weeks
Injection technique

No sexual intercourse for 2 weeks after the injection

10 ml lignocaine 1%
Results

28 patients completed 3 treatment cycles

- Improvement: 26
- No change: 2
Results

Mean Curvature reduction
-18.56° (0°-40°)
-33% (0-60%)
P<0.001

Degree

53.9 (30-90)°

Baseline

38.4 (27-75)°

12 Weeks

Baseline

12 Weeks
Results

Patients Grouped according to Severity of Penile Curvature

<table>
<thead>
<tr>
<th>Mean Curvature</th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>15°-30°</td>
<td>30°</td>
<td>12°</td>
</tr>
<tr>
<td>31°-45°</td>
<td>41°</td>
<td>29°</td>
</tr>
<tr>
<td>46°-60°</td>
<td>55°</td>
<td>37°</td>
</tr>
<tr>
<td>61°-75°</td>
<td>68°</td>
<td>43°</td>
</tr>
<tr>
<td>76°-90°</td>
<td>83°</td>
<td>60°</td>
</tr>
</tbody>
</table>

N=1, N=6, N=10, N=3
Results

IIEF Questionnaire

<table>
<thead>
<tr>
<th></th>
<th>Baseline</th>
<th>Follow-up</th>
</tr>
</thead>
<tbody>
<tr>
<td>IIEF-EF</td>
<td>20.13</td>
<td>22.19</td>
</tr>
<tr>
<td>IIEF-OF</td>
<td>7.06</td>
<td>7.83</td>
</tr>
<tr>
<td>IIEF-SD</td>
<td>7.05</td>
<td>7.32</td>
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<tr>
<td>IIEF-IS</td>
<td>6.56</td>
<td>8.56</td>
</tr>
<tr>
<td>IIEF-OS</td>
<td>3.7</td>
<td>6.25</td>
</tr>
</tbody>
</table>

*p < 0.05, p = 0.05, p = 0.08, p < 0.001, p = 0.161*
Results

PDQ-Questionnaire

- PDQ-PP: Baseline 10.13, Follow-up 8.25
- PDQ-PD: Baseline 2.75, Follow-up 1.75
- PDQ-BD: Baseline 8.44, Follow-up 6.06

Statistical significances:
- PDQ-PP: p < 0.05
- PDQ-BD: p = 0.294
Results

Global Assessment of Peyronie’s Disease Questionnaire

- A little worse: n=1
- Stayed the same: n=3
- A small but important improvement: n=6
- Moderately improved: n=9
- Much improved: n=9
Results

• Five patients requested 3 more injections continued to have additional curvature improvement, mean 10.4°(0°-30°).

• Only mild transient local side effects seen in all patients in the form of penile swelling and bruising.

• No incidence of corporal rupture.

• No systemic adverse events.
Results

The new shortened protocol using 3 CCH injections is safe, effective and will reduce the cost and duration of treatment.