Treatment Naïve, Chronic HCV

Peginterferon alfa-2a +/- Ribavirin for Chronic HCV

Peginterferon alfa-2a +/- Ribavirin for Chronic HCV Study Design

• **Study**
  - Open-label randomized controlled trial

• **Subjects**
  - N = 1149 with chronic hepatitis C randomized
  - Treatment naïve; 62% genotype 1
  - Serum ALT above upper limit of normal x prior 6 months

• **Regimens (48 Week Treatment)**
  - Peginterferon alfa-2a 180 µg 1x/week + Ribavirin 1000-1200 mg/day
  - Peginterferon alfa-2a 180 µg 1x/week + Placebo
  - Interferon alfa-2b 3 million U 3x/week + Ribavirin 1000-1200 mg/day

• **Primary Endpoint**
  - Undetectable serum HCV RNA 24 weeks after stopping treatment

*Ribavirin dosing: <75 kg = 1000 mg/day; ≥75 kg = 1200 mg/day

Peginterferon alfa-2a +/- Ribavirin for Chronic HCV Study Design

<table>
<thead>
<tr>
<th>Week</th>
<th>0</th>
<th>48</th>
<th>72</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>453</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peginterferon alfa-2a + Ribavirin</td>
<td>SVR24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>224</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Peginterferon alfa-2a + Placebo</td>
<td>SVR24</td>
<td></td>
<td></td>
</tr>
<tr>
<td>N</td>
<td>444</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standard interferon + Ribavirin</td>
<td>SVR24</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Drug Dosing
Peginterferon alfa-2a 180 µg 1x/week
Weight-based Ribavirin (divided bid): 1000 mg/day if < 75kg or 1200 mg/day if ≥ 75kg
Interferon alfa-2b 3 million U 3x/week

Peginterferon alfa-2a + Ribavirin for Chronic HCV: Results

Response after 48 Weeks of Treatment

<table>
<thead>
<tr>
<th>Group</th>
<th>End of Treatment Response</th>
<th>Sustained Virologic Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peginterferon alfa-2a 180 µg + Ribavirin</td>
<td>69/453 (132/224)</td>
<td>56/453 (255/453)</td>
</tr>
<tr>
<td>Peginterferon alfa-2a 180 µg + Placebo</td>
<td>59/453 (231/444)</td>
<td>29/453 (66/224)</td>
</tr>
<tr>
<td>Interferon alfa-2b + Ribavirin</td>
<td>52/453 (197/444)</td>
<td>44/453 (197/444)</td>
</tr>
</tbody>
</table>

Peginterferon alfa-2a + Ribavirin for Chronic HCV
Predictive Value of Early Virologic Response

Week 12
HCV RNA (N = 453)

2-log drop or undetectable HCV RNA

Yes
N = 390 (86%)

SVR
N = 253 (65%)
No SVR
N = 137 (35%)

No
N = 63 (14%)

SVR
N = 2 (3%)
No SVR
N = 61 (97%)

Conclusions: “In patients with chronic hepatitis C, once-weekly peginterferon alfa-2a plus ribavirin was tolerated as well as interferon alfa-2b plus ribavirin and produced significant improvements in the rate of sustained virologic response, as compared with interferon alfa-2b plus ribavirin or peginterferon alfa-2a alone.”

This slide deck is from the University of Washington’s *Hepatitis C Online* and *Hepatitis Web Study* projects.

Hepatitis C Online  
[www.hepatitisc.uw.edu](http://www.hepatitisc.uw.edu)

Hepatitis Web Study  

Funded by a grant from the Centers for Disease Control and Prevention.