Treatment Naïve, Chronic HCV

Peginterferon alfa-2a+/- Ribavirin *versus* Interferon alfa-2b + Ribavirin

Peginterferon +/- Ribavirin versus Interferon + Ribavirin
Study Features

- **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 +/- Ribavirin versus Interferon + Ribavirin Study Design

- **Week 0**: N = 453, Peginterferon alfa-2a + Ribavirin (SVR24)
- **Week 48**: N = 224, Peginterferon alfa-2a + Placebo (SVR24)
- **Week 72**: N = 444, Interferon alfa-2b + Ribavirin (SVR24)

**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 +/- Ribavirin versus Interferon + Ribavirin

Virologic Responses, by Treatment Regimen

<table>
<thead>
<tr>
<th>Treatment Regimen</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>69/313 (453)</td>
<td>56/255 (453)</td>
</tr>
<tr>
<td>Peginterferon alfa-2a 180 µg + Placebo</td>
<td>59/132 (224)</td>
<td>29/66 (224)</td>
</tr>
<tr>
<td>Interferon alfa-2b + Ribavirin</td>
<td>52/231 (444)</td>
<td>44/197 (444)</td>
</tr>
</tbody>
</table>

P < 0.001 (for all comparisons)

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**


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