Duration and Dose Finding Peginterferon alfa-2a + Ribavirin

Randomized study of low-dose versus weight based ribavirin and 24 versus 48 weeks of therapy

Peginterferon alfa-2a + Ribavirin for Chronic HCV Treatment Duration and Ribavirin Dose

- **Study**
  - Randomized, double-blind trial, with 2 x 2 factorial design

- **Subjects**
  - N = 1311 with chronic hepatitis C (1284 treated)
  - Treatment naïve adult patients; 58% genotype 1
  - Serum ALT above upper limit of normal x prior 6 months

- **Regimens**
  - Peginterferon alfa-2a: 180 μg/wk + Ribavirin: 800 mg/day x 24 wks
  - Peginterferon alfa-2a: 180 μg/wk + *Ribavirin: 1000-1200 mg/day x 24 wks
  - Peginterferon alfa-2a: 180 μg/wk + Ribavirin: 800 mg/d x 48 weeks
  - Peginterferon alfa-2a: 180 μg/wk + *Ribavirin: 1000-1200 mg/day x 48 wks

- **Primary Endpoint**
  - Undetectable serum HCV RNA at end of treatment (ETR)
  - Undetectable serum HCV RNA 24 wks after cessation of treatment (SVR)

*Ribavirin dose: Ribavirin 1000 mg/day for Wt <75 kg, 1200 mg/day for Wt ≥75 kg

<table>
<thead>
<tr>
<th>Week 0</th>
<th>12</th>
<th>24</th>
<th>48</th>
<th>72</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Peginterferon alfa-2a + Ribavirin (low dose) (n = 214)</td>
<td>SVR24</td>
<td>SVR24</td>
<td>SVR24</td>
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<tr>
<td></td>
<td>Peginterferon alfa-2a + Ribavirin (weight-based dose) (n = 288)</td>
<td>SVR24</td>
<td>SVR24</td>
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<tr>
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<td>Peginterferon alfa-2a + Ribavirin (low dose) (n = 365)</td>
<td>SVR24</td>
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<tr>
<td></td>
<td>Peginterferon alfa-2a + Ribavirin (weight-based dose) (n = 444)</td>
<td>SVR24</td>
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</tbody>
</table>

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SVR24 Rates, by Regimen

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Rates of SVR with Different Peginterferon + Ribavirin Regimens

- Peginterferon + Ribavirin (low dose) x 24 weeks
- Peginterferon + Ribavirin (weight-based dose) x 24 weeks
- Peginterferon + Ribavirin (low dose) x 48 weeks
- Peginterferon + Ribavirin (weight-based dose) x 48 weeks

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**Conclusion:** “Treatment with peginterferon-alpha2a and ribavirin may be individualized by genotype. Patients with HCV genotype 1 require treatment for 48 weeks and a standard dose of ribavirin; those with HCV genotypes 2 or 3 seem to be adequately treated with a low dose of ribavirin for 24 weeks.”

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

**Hepatitis C Online**
www.hapatitisc.uw.edu

**Hepatitis Web Study**
http://depts.washington.edu/hepstudy/

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