Early versus delayed treatment of acute hepatitis C: Final results of the randomized controlled German HEP-NET acute HCV-III study


Abstract #48

Study design – Acute HCV – III Study

Symptoms

randomization 1:1

PEG-IFNα-2b 1.5 µg/kg
24 weeks

FU 24 weeks

PEG-IFNα-2b 1.5 µg/kg
Ribavirin > 10.6 mg/ kg
24 weeks

FU 24 weeks

Asymp. HCV

HCV-RNA pos

PEG-IFNα-2b 1.5 µg/kg
24 weeks

FU 24 weeks

HCV-RNA neg

24 weeks wait and see

PEG-IFNα-2b 1.5 µg/kg
Ribavirin > 10.6 mg/ kg
24 weeks

FU 24 weeks

wait and see

Acute HCV – III Study, EASL 2012
Baseline Characteristics

<table>
<thead>
<tr>
<th>Study Cohort</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Patients (n)</td>
<td>132</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>77 (58%)</td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>55 (42%)</td>
</tr>
<tr>
<td>Age (years), Median</td>
<td>39 (19-70)</td>
</tr>
<tr>
<td>Genotype</td>
<td></td>
</tr>
<tr>
<td>Genotype 1</td>
<td>87 (66%)</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>11 (8%)</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>24 (18%)</td>
</tr>
<tr>
<td>Genotype 4</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Other Genotype</td>
<td>1 (1%)</td>
</tr>
<tr>
<td>Genotype not applicable</td>
<td>8 (6%)</td>
</tr>
</tbody>
</table>

Virological Response Immediate Treatment (A + C)

- Patients, HCV-RNA negative (%)
  - FU 24 - Intent to treat: 75 (Arm C), 76 (Arm A)
  - FU 24 - patients adherent to therapy (completer): 95 (Arm C), 90 (Arm A)
Delayed Treatment – Arm B

Arm B, patients with symptoms
n = 52

12 weeks observation period

Lost to follow-up n = 7
Drop out n = 1

HCV-RNA negative
n = 22

Lost to follow-up n = 4
Drop out n = 1

HCV-RNA positive
n = 22

Factors associated with HCV - Negativity at week 12:

- Female gender
- HCV - Genotype 1

No association with IL28B-Genotype

Week 60 completer
SVR n = 11
relapse after week 36 n = 2

Study week 36

HCV-RNA positive
n = 22

PEG-IFNα-2b + Ribavirin
24 weeks n = 18

Treatment completed n = 15
HCV-RNA negative n = 15

Lost to follow-up n = 1

FU 24 completer

Acute HCV – III Study, EASL 2012
1 patient was not treated with IFN due to diagnosis of bronchial carcinoma

Conclusion

This so far largest prospective and the first randomized European trial on acute hepatitis C confirmed that early immediate treatment with PEG-IFN alpha-2b is highly effective in both symptomatic and asymptomatic patients.

Delayed PEG-IFN alpha-2b + ribavirin treatment resulted in lower overall response rates in this real-life treatment setting (ITT).

However, if adherence can be assured delayed combination therapy seems to be of similar efficacy in symptomatic patients and might be recommended in particular for women infected with genotype 1.