Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy

C-EDGE CO-STAR

Elbasvir-Grazoprevir in HCV GT 1, 4, or 6 in PWID on Opiate Agonist Therapy
C-EDGE CO-STAR: Study Features

- **Design**: Randomized, phase 3, placebo-controlled, double-blind, multi-site trial using a fixed-dose combination of elbasvir-grazoprevir in treatment-naïve chronic HCV genotype 1, 4, or 6 in persons who inject drugs who are receiving opiate agonist therapy

- **Entry Criteria**
  - Chronic HCV Genotype 1, 4, or 6
  - No prior treatment
  - 18 years or older
  - Opiate Agonist Therapy for ≥3 months and kept ≥ 80% of appointments
  - HCV RNA ≥10,000 IU/mL
  - Cirrhosis allowed with goal 20% of subjects with cirrhosis
  - HIV infection allowed

- **Primary End-Point**: SVR12

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C-EDGE CO-STAR: Study Features

**Drug Dosing**

Grazoprevir-elbasvir (100/50 mg): fixed dose combination; one pill once daily

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C-EDGE CO-STAR: Results in Immediate-Treatment Group

C-EDGE CO-STAR: SVR12 Results (Assumes Reinfections are Failures)

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C-EDGE CO-STAR: Results in Immediate-Treatment Group

C-EDGE CO-STAR: SVR12 Results (Assumes Reinfections are Responses)

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C-EDGE CO-STAR: Results in Deferred-Treatment Group

C-EDGE CO-STAR: SVR12 Results (Assumes Reinfections are Failures)

<table>
<thead>
<tr>
<th>Patients with SVR12</th>
<th>All GT</th>
<th>GT1a*</th>
<th>GT1b</th>
<th>GT4</th>
<th>GT6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>90% (95% CI, 81-96)</td>
<td>90% (95% CI, 66-100)</td>
<td>93% (95% CI, 54-100)</td>
<td>100% (95% CI, 62-100)</td>
<td>50% (95% CI, 7-93)</td>
</tr>
<tr>
<td></td>
<td>85/95</td>
<td>64/71</td>
<td>13/14</td>
<td>6/6</td>
<td>2/4</td>
</tr>
</tbody>
</table>