Compassionate Use of Remdesivir for Patients with Severe COVID-19 (International)

Compassionate Use of Remdesivir for Patients with Severe Covid-19: Design

**Study Design**

- **Background**: Case series of 61 patients diagnosed with severe COVID-19 infection who received remdesivir through compassionate use from January 25, 2020 to March 7, 2020 in multiple international sites.

- **Evaluation**: Incidence of key clinical endpoints (multiple).

- **Inclusion Criteria (enrolled, n = 61; final analysis, n = 53)**
  - PCR positive for SARS-CoV-2 in nasopharyngeal sample
  - SpO2 ≤94% on room air, or need for oxygen support
  - Creatinine clearance >30 mL per minute
  - AST and ALT <5x the upper limit of normal

- **Exclusion Criteria**
  - Use of other investigational agent for COVID-19

- **Planned Treatment**
  - Remdesivir: 200 mg IV loading dose on day 1, then 100 mg IV daily x 9 days (total 10 days)
  - Standard supportive care

- **Duration of follow up**
  - 28 days

Compassionate Use of Remdesivir for Patients with Severe Covid-19: Baseline Characteristics

<table>
<thead>
<tr>
<th>Baseline Characteristics*</th>
<th>Invasive Ventilation (n = 34)</th>
<th>Non-Invasive O2 Support (n = 19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (median, IQR, years)</td>
<td>67 (56 - 72)</td>
<td>53 (41-68)</td>
</tr>
<tr>
<td>Male, n (%)</td>
<td>27 (79)</td>
<td>13 (68)</td>
</tr>
<tr>
<td>Coexisting conditions, n (%)</td>
<td>25 (74)</td>
<td>11 (58)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>9 (26)</td>
<td>4 (21)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>8 (24)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Hyperlipidemia</td>
<td>6 (18)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>Asthma</td>
<td>5 (15)</td>
<td>1 (5)</td>
</tr>
<tr>
<td>Duration of symptoms prior to remdesivir (median, IQR, days)</td>
<td>11 (8 – 15)</td>
<td>13 (10 – 14)</td>
</tr>
</tbody>
</table>

*Of the 61 patients approved for compassionate use remdesivir, 7 were excluded from analysis due to lack of baseline information and 1 was excluded due to an error in remdesivir dosing

Compassionate Use of Remdesivir for Patients with Severe Covid-19: Baseline Oxygen Support

<table>
<thead>
<tr>
<th>Baseline Characteristics*</th>
<th>Invasive Ventilation (n = 34)</th>
<th>Non-invasive O2 Support (n = 19)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oxygen Support Category, n (%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Invasive mechanical ventilation</td>
<td>30 (88)</td>
<td>NA</td>
</tr>
<tr>
<td>Extracorporeal membrane oxygenation (ECMO)</td>
<td>4 (12)</td>
<td>NA</td>
</tr>
<tr>
<td>Noninvasive positive-pressure ventilation</td>
<td>NA</td>
<td>2 (11)</td>
</tr>
<tr>
<td>High-flow oxygen</td>
<td>NA</td>
<td>5 (26)</td>
</tr>
<tr>
<td>Low-flow oxygen</td>
<td>NA</td>
<td>10 (53)</td>
</tr>
<tr>
<td>Ambient air</td>
<td>NA</td>
<td>2 (11)</td>
</tr>
</tbody>
</table>

*Of the 61 patients approved for compassionate use remdesivir, 7 were excluded from analysis due to lack of baseline information and 1 was excluded due to an error in remdesivir dosing

Compassionate Use of Remdesivir for Patients with Severe Covid-19: Results (Overall)

Note: in this analysis shown below, death was not considered a treatment failure and the cumulative incidence of clinical improvement was 84% when. When death considered failure, the cumulative incidence of clinical improvement was 74%.

Clinical improvement defined as decrease of ≥2 points on 6-point ordinal scale or live discharge.

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Compassionate Use of Remdesivir for Patients with Severe Covid-19: Results (Baseline O2 Support)

Clinical improvement defined as decrease of ≥2 points on 6-point ordinal scale or live discharge

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Clinical improvement defined as decrease of ≥2 points on 6-point ordinal scale or live discharge

32 patients (60%) reported adverse events most commonly:
- Increased hepatic enzymes
- Diarrhea
- Rash
- Renal impairment
- Hypotension

4 patients (8%) discontinued remdesivir:
- 1 due to worsened renal failure
- 1 due to multiorgan failure
- 2 due to elevated aminotransferase levels

**Conclusions:** “In this cohort of patients hospitalized for severe Covid-19 who were treated with compassionate-use remdesivir, clinical improvement was observed in 36 of 53 patients (68%). Measurement of efficacy will require ongoing randomized, placebo-controlled trials of remdesivir therapy.”