**Study Design**  
Multicenter, open-label, parallel group, superiority, RCT – **Severe/Critical COVID-19 – (1:1)**

**Location**  
Brazil – 9 hospitals

**Inclusion**  
Severe/Critical COVID-19 pneumonia + Need of O2 to keep SpO2 >93% or MV <24h + at least 2 elevated biomarkers #(CRP >5mg/dL; Ferritin > 300μg/L; D-dimer > 1000 ng/mL; LDH >ULN)

**Exclusion**  
AST or ALT increased 5 x ULN, Glomerular filtration rate <30 mL/min/1.72m²

**Intervention**  
Tocilizumab 8 mg/kg IV (up to 800 mg)

**Control**  
Standard of care

<table>
<thead>
<tr>
<th>Primary Outcomes</th>
<th>Tocilizumab n=65</th>
<th>Control n=64</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical status at day 15 on 7-level ordinal scale#</td>
<td>12%</td>
<td>19%</td>
</tr>
<tr>
<td>Death/MV at day 15</td>
<td>28%</td>
<td>20%</td>
</tr>
<tr>
<td>In-hospital mortality</td>
<td>21%***</td>
<td>9%</td>
</tr>
<tr>
<td>Death at day 15</td>
<td>17%***</td>
<td>3%</td>
</tr>
<tr>
<td>Death at day 28</td>
<td>21%***</td>
<td>9%</td>
</tr>
</tbody>
</table>

**Comments:**  
Trial ended prematurely after first interim analysis due to the number of deaths at 15 days in the tocilizumab group.  
*** p<0.05 compared to control group  
# 7-level ordinal scale (1, discharged/ready for discharge; 7, death)  
Corticosteroids within 7 days prior to first dose was 84% in the tocil arm and 89% in the control arm.

**Abbreviations:**  
AST, aspartate aminotransferase; ALT, alanine aminotransferase; CRP, C-reactive protein; LDH, lactate dehydrogenase; MV, mechanical ventilation; O₂, oxygen; RCT, randomized controlled trial; ULN, upper limit of normal.