TAMEST COVID-19 Webinar
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June 11, 2020
Therapeutic Targets

# Clinical Trials: UT Southwestern & PHHS

<table>
<thead>
<tr>
<th><strong>Gilead</strong>: remdesivir</th>
<th><strong>Regeneron</strong>: sarilumab</th>
<th><strong>HERO</strong>: hydroxychloroquine</th>
<th><strong>NIH ACTT2</strong>: remdesivir +/- baricitinib</th>
</tr>
</thead>
<tbody>
<tr>
<td>Moderate; hospitalized</td>
<td>Severe; hospitalized</td>
<td>Severe to critical; hospitalized</td>
<td>Prevention; outpatient</td>
</tr>
</tbody>
</table>

**Inclusion:**
- + COVID ≤ 4 days
- SpO2 >94% on room air
- Pulmonary infiltrates

**Exclusion:**
- Participation in other COVID-19 trials
- ALT or AST >5X ULN
- Cr Cl <50 ml/min
- Pregnancy/breastfeeding
- Treatment with other COVID-19 antivirals < 24 hours
- Mechanical ventilation

**Group 1**: 5 days  
**Group 2**: 10 days  
**Group 3**: standard of care

<table>
<thead>
<tr>
<th><strong>Enrolled 25 patients</strong></th>
<th><strong>Enrolled: 135</strong></th>
<th><strong>Enrolled: 36</strong></th>
<th><strong>Enrolled: 12</strong></th>
<th><strong>Enrolled: 7</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed</td>
<td>Closed</td>
<td>Open</td>
<td>Open</td>
<td>Open</td>
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</table>

**Group 1**: 200 mg.  
**Group 2**: 400 mg.  
**Group 3**: placebo

<table>
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<tr>
<th><strong>Phase 2</strong>:</th>
<th><strong>Phase 3</strong>:</th>
<th><strong>hydroxychloroquine 30 days vs placebo</strong></th>
<th><strong>remdesivir vs. remdesivir +baricitinib</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Group 1</strong>: 200 mg.</td>
<td><strong>Cohort 1</strong>: 400 mg</td>
<td></td>
<td></td>
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<tr>
<td><strong>Group 2</strong>: 400 mg.</td>
<td><strong>Cohort 2</strong>: 800 mg</td>
<td></td>
<td></td>
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<tr>
<td><strong>Group 3</strong>: placebo</td>
<td><strong>Cohort 3</strong>: 800 mg</td>
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Challenges of Clinical Trials During a Pandemic

• (1) Lack of knowledge of why we need to do clinical trials
  • I want a drug that works
  • I don’t want to be a “guinea pig”
  • I am afraid of the side effects

• (2) Is it ethical to give a placebo?

• (3) Infrastructure to scale up clinical trials
  • Research coordinators, data collection and entry, monitoring and reporting

• (3) Language barriers

• (4) consenting and working remotely
  • Lack of PPE, fear among research staff to see COVID-19 patients
Repurposed Drugs for COVID-19


Hung et al. Lancet 2020 https://doi.org/10.1016/S0140-6736(20)31042-4
