Table 2d. Ivermectin: Selected Clinical Data

Last Updated: April 29, 2022

The clinical trials described in this table are RCTs that had the greatest impact on the Panel’s recommendation. The Panel reviewed other clinical studies of IVM for the treatment of COVID-19. However, those studies have limitations that make them less definitive and informative than the studies summarized in the table.

<table>
<thead>
<tr>
<th>Methods</th>
<th>Results</th>
<th>Limitations and Interpretation</th>
</tr>
</thead>
</table>
| **TOGETHER**: Double-Blind, Adaptive, RCT of Ivermectin in Nonhospitalized Patients With COVID-19 in Brazil

**Key Inclusion Criteria:**
- Positive SARS-CoV-2 antigen test
- Within 7 days of symptom onset
- ≥1 high-risk factor for disease progression (e.g., aged >50 years, comorbidities, immunosuppression)

**Interventions:**
- IVM 400 μg/kg PO per day for 3 days (n = 679)
- Placebo (n = 679; not all participants received IVM placebo)

**Primary Endpoint:**
- Composite of emergency setting observation >6 hours or hospitalized for COVID-19 within 28 days of randomization

**Participant Characteristics:**
- Median age 49 years; 46% aged ≥50 years; 58% women; 95% “mixed race”
- Most prevalent risk factor: 50% with obesity
- Symptom onset: 44% within 3 days

**Primary Outcome:**
- Composite of emergency setting observation >6 hours or hospitalized within 28 days of randomization (ITT): 100 (14.7%) in IVM arm vs. 111 (16.4%) in placebo arm (relative risk 0.90; 95% CrI, 0.70–1.16)
- 171 (81%) of all events were hospitalizations (ITT)

**Secondary Outcomes:**
- No difference between IVM and placebo arms in:
  - Viral clearance at Day 7 (relative risk 1.00; 95% CrI, 0.68–1.46)
  - All-cause mortality: 21 (3.1%) vs. 24 (3.5%) (relative risk 0.88; CrI, 0.49–1.55)
  - Occurrence of AEs

**Key Limitations:**
- Health care facility capacity may have influenced the number and duration of emergency setting visits and hospitalizations.
- No details on safety outcomes (e.g., type of treatment-emergent AEs) other than grading were reported.

**Interpretation:**
- In outpatients with recent COVID-19 infection, IVM did not reduce the need for emergency setting visits or hospitalization when compared with placebo.
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<thead>
<tr>
<th>Methods</th>
<th>Results</th>
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</thead>
<tbody>
<tr>
<td><strong>IVERCOR-COVID19</strong>: Double-Blind, Placebo-Controlled, Randomized Trial of Ivermectin in Nonhospitalized Patients With COVID-19 in Argentina(^{28})</td>
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<tr>
<td><strong>Key Inclusion Criterion:</strong></td>
<td><strong>Participant Characteristics:</strong></td>
<td><strong>Key Limitation:</strong></td>
</tr>
<tr>
<td>• Positive SARS-CoV-2 RT-PCR result within 48 hours of screening</td>
<td>• Mean age 42 years; 8% aged (\geq) 65 years; 47% women</td>
<td>• Enrolled a fairly young population with few of the comorbidities that predict disease progression.</td>
</tr>
<tr>
<td><strong>Key Exclusion Criteria:</strong></td>
<td>• 24% with HTN; 10% with DM; 58% with (\geq) 1 comorbidity</td>
<td><strong>Interpretation:</strong></td>
</tr>
<tr>
<td>• Oxygen supplementation or hospitalization</td>
<td>• Median time from symptom onset: 4 days</td>
<td>• Among patients who had recently acquired SARS-CoV-2 infection, there was no evidence that IVM provided any clinical benefit.</td>
</tr>
<tr>
<td>• Concomitant use of CQ or HCQ</td>
<td><strong>Interventions:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Interventions:</strong></td>
<td>• Weight-based dose of IVM PO at enrollment and 24 hours later for a maximum total dose of 48 mg (n = 250)</td>
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<tr>
<td>• Placebo (n = 251)</td>
<td>• Placebo (n = 251)</td>
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</tr>
<tr>
<td><strong>Primary Endpoint:</strong></td>
<td><strong>Primary Endpoint:</strong></td>
<td></td>
</tr>
<tr>
<td>• Hospitalization for any reason</td>
<td>• Hospitalization for any reason: 5.6% in IVM arm vs. 8.3% in placebo arm (OR 0.65; 95% CI, 0.32–1.31; (P = 0.23))</td>
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</tr>
<tr>
<td><strong>Key Secondary Endpoints:</strong></td>
<td><strong>Secondary Outcomes:</strong></td>
<td></td>
</tr>
<tr>
<td>• Need for MV</td>
<td>• Need for MV: 2% in IVM arm vs. 1% in placebo arm ((P = 0.7))</td>
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<tr>
<td>• All-cause mortality</td>
<td>• All-cause mortality: 2% in IVM arm vs. 1% in placebo arm ((P = 0.7))</td>
<td></td>
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<tr>
<td>• Occurrence of AEs</td>
<td>• Occurrence of AEs: 18% in IVM arm vs. 21% in placebo arm ((P = 0.6))</td>
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</tbody>
</table>
### Methods

**I-TECH: Open-Label RCT of Ivermectin in Patients With Mild to Moderate COVID-19 in Malaysia**

<table>
<thead>
<tr>
<th>Key Inclusion Criteria:</th>
<th>Participant Characteristics:</th>
<th>Key Limitation:</th>
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</thead>
<tbody>
<tr>
<td>Positive SARS-CoV-2 RT-PCR or antigen test result within 7 days of symptom onset</td>
<td>• Mean age 63 years; 55% women</td>
<td>• Open-label study</td>
</tr>
<tr>
<td>Aged ≥50 years</td>
<td>• 68% received ≥1 dose COVID-19 vaccine; 52% received 2 doses</td>
<td>Interpretation:</td>
</tr>
<tr>
<td>≥1 comorbidity</td>
<td>• Most common comorbidities: 75% with HTN; 54% with DM; 24% with dyslipidemia</td>
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</tr>
<tr>
<td><strong>Key Exclusion Criteria:</strong></td>
<td>• Mean duration of symptoms: 5 days</td>
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<tr>
<td>Required supplemental oxygen</td>
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<td></td>
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<tr>
<td>Severe hepatic impairment (ALT &gt;10 times the ULN)</td>
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<tr>
<td><strong>Interventions:</strong></td>
<td></td>
<td></td>
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<tr>
<td>IVM: 400 μg/kg PO daily for 5 days plus SOC (n = 241)</td>
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<tr>
<td>SOC (n = 249)</td>
<td></td>
<td></td>
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<tr>
<td><strong>Primary Endpoint:</strong></td>
<td></td>
<td></td>
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<tr>
<td>Progression to severe COVID-19 (i.e., hypoxia requiring supplemental oxygen to maintain SpO₂ ≥95%)</td>
<td></td>
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<tr>
<td><strong>Key Secondary Endpoints:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>In-hospital, all-cause mortality by Day 28</td>
<td></td>
<td></td>
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<tr>
<td>MV or ICU admission</td>
<td></td>
<td></td>
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<tr>
<td>Occurrence of AEs</td>
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</tbody>
</table>

### Results

**Primary Outcome:**
- Progression to severe COVID-19 (mITT): 52 (21.6%) in IVM plus SOC arm vs. 43 (17.3%) in SOC alone arm (relative risk 1.25; 95% CI, 0.87–1.80; \( P = 0.25 \))

**Secondary Outcomes:**
- In-hospital, all-cause mortality: 3 (1.2%) vs. 10 (4.0%) (relative risk 0.31; 95% CI, 0.09–1.11; \( P = 0.09 \))
- MV: 4 (1.7%) vs. 10 (4.0%) (relative risk 0.41; 95% CI, 0.13–1.30; \( P = 0.17 \))
- ICU admission: 6 (2.5%) vs. 8 (3.2%) (relative risk 0.78; 95% CI, 0.27–2.20; \( P = 0.79 \))
- Occurrence of AEs: 33 (13.7%) in the IVM plus SOC arm vs. 11 (4.4%) in the SOC alone arm; most with diarrhea (14 vs. 4)
<table>
<thead>
<tr>
<th>Methods</th>
<th>Results</th>
<th>Limitations and Interpretation</th>
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<tbody>
<tr>
<td><strong>Double-Blind, Placebo-Controlled, Randomized Trial of Ivermectin in Patients With Mild COVID-19 in Colombia</strong>&lt;sup&gt;30&lt;/sup&gt;</td>
<td></td>
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<tr>
<td><strong>Key Inclusion Criteria:</strong></td>
<td>• Median age 37 years; 4% aged ≥65 years in IVM arm, 8% in placebo arm; 39% men in IVM arm, 45% in placebo arm</td>
<td><strong>Key Limitations:</strong></td>
</tr>
<tr>
<td>• Positive SARS-CoV-2 RT-PCR or antigen test result</td>
<td>• 79% with no known comorbidities</td>
<td>• Due to low event rates, the primary endpoint changed from the proportion of patients with clinical deterioration to the time to symptom resolution during the trial.</td>
</tr>
<tr>
<td>• Symptoms ≤7 days</td>
<td>• Median symptom onset to randomization: 5 days</td>
<td>• The study enrolled younger, healthier patients, a population that does not typically develop severe COVID-19.</td>
</tr>
<tr>
<td>• Mild disease</td>
<td><strong>Primary Endpoint:</strong></td>
<td><strong>Interpretation:</strong></td>
</tr>
<tr>
<td><strong>Key Exclusion Criteria:</strong></td>
<td>• Median time to symptom resolution: 10 days in IVM arm vs. 12 days in placebo arm (HR 1.07; P = 0.53)</td>
<td>• In patients with mild COVID-19, IVM 300 μg/kg per day for 5 days did not improve the time to resolution of symptoms.</td>
</tr>
<tr>
<td>• Asymptomatic disease</td>
<td>• Symptoms resolved by Day 21: 82% in IVM arm vs. 79% in placebo arm</td>
<td></td>
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<tr>
<td>• Severe pneumonia</td>
<td><strong>Secondary Outcomes:</strong></td>
<td></td>
</tr>
<tr>
<td>• Hepatic dysfunction</td>
<td>• Clinical deterioration: no difference between arms</td>
<td></td>
</tr>
<tr>
<td><strong>Interventions:</strong></td>
<td>• Escalation of care: no difference between arms</td>
<td></td>
</tr>
<tr>
<td>• IVM 300 μg/kg PO per day for 5 days (n = 200)</td>
<td>• Occurrence of AEs:</td>
<td></td>
</tr>
<tr>
<td>• Placebo PO (n = 198)</td>
<td>• Discontinued treatment due to AEs: 8% in IVM arm vs. 3% in placebo arm</td>
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<tr>
<td><strong>Primary Endpoint:</strong></td>
<td>• No SAEs were related to intervention</td>
<td></td>
</tr>
<tr>
<td>• Time to resolution of symptoms within 21 days</td>
<td><strong>Key Secondary Endpoints:</strong></td>
<td></td>
</tr>
<tr>
<td><strong>Key Secondary Endpoints:</strong></td>
<td>• Clinical deterioration</td>
<td></td>
</tr>
<tr>
<td>• Clinical deterioration</td>
<td>• Escalation of care</td>
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<tr>
<td>• Escalation of care</td>
<td>• Occurrence of AEs:</td>
<td></td>
</tr>
<tr>
<td>• Occurrence of AEs</td>
<td>• Discontinued treatment due to AEs: 8% in IVM arm vs. 3% in placebo arm</td>
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</tbody>
</table>
### Open-Label RCT of Ivermectin in Hospitalized Patients With COVID-19 in Egypt

<table>
<thead>
<tr>
<th>Methods</th>
<th>Results</th>
<th>Limitations and Interpretation</th>
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</thead>
<tbody>
<tr>
<td><strong>Key Inclusion Criteria:</strong>&lt;br&gt;- RT-PCR-confirmed SARS-CoV-2 infection by pharyngeal swab&lt;br&gt;- Hospitalized with mild to moderate COVID-19</td>
<td><strong>Participant Characteristics:</strong>&lt;br&gt;- Mean age 42 years for IVM arm, 39 years for SOC arm; 50% men&lt;br&gt;- 49% with ≥1 comorbidity</td>
<td><strong>Key Limitation:</strong>&lt;br&gt;- Small, open-label study</td>
</tr>
<tr>
<td><strong>Key Exclusion Criterion:</strong>&lt;br&gt;- Cardiac problems</td>
<td><strong>Primary Outcome:</strong>&lt;br&gt;- All-cause mortality by 28 days: 3 (3.7%) in IVM arm vs. 4 (4.9%) in SOC arm ($P = 1.00$)</td>
<td><strong>Interpretation:</strong>&lt;br&gt;- Use of IVM, when compared with the SOC, did not result in differences in all-cause mortality, hospital LOS, or the need for MV.</td>
</tr>
<tr>
<td><strong>Interventions:</strong>&lt;br&gt;- IVM 12 mg PO once daily for 3 days ($n = 82$)&lt;br&gt;- SOC ($n = 82$)</td>
<td><strong>Secondary Outcomes:</strong>&lt;br&gt;- Mean hospital LOS: 9 days in IVM arm vs. 11 days in SOC arm ($P = 0.085$)&lt;br&gt;- Need for MV: 3 (3.7%) in each arm ($P = 1.00$)</td>
<td></td>
</tr>
<tr>
<td><strong>Primary Endpoint:</strong>&lt;br&gt;- All-cause mortality by 28 days</td>
<td><strong>Key Secondary Endpoints:</strong>&lt;br&gt;- Hospital LOS&lt;br&gt;- Need for MV</td>
<td></td>
</tr>
<tr>
<td><strong>Key Secondary Endpoints:</strong>&lt;br&gt;- Hospital LOS&lt;br&gt;- Need for MV</td>
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</table>
## Methods

**Double-Blind, Placebo-Controlled, Randomized Trial of Ivermectin in Patients With Mild to Moderate COVID-19 in India**

**Key Inclusion Criteria:**
- Positive SARS-CoV-2 RT-PCR or antigen test result
- Hospitalized with mild or moderate COVID-19

**Interventions:**
- IVM 12 mg PO for 2 days (n = 55)
- Placebo PO (n = 57)

**Primary Endpoint:**
- Negative SARS-CoV-2 RT-PCR result on Day 6

**Key Secondary Endpoints:**
- Symptom resolution by Day 6
- Discharge by Day 10
- Need for ICU admission or MV
- In-hospital mortality

## Results

**Participant Characteristics:**
- Mean age 53 years; 28% women
- 35% with HTN; 36% with DM
- 79% with mild COVID-19
- Mean 6.9 days from symptom onset
- 100% received HCQ, steroids, and antibiotics; 21% received RDV; 6% received tocilizumab

**Primary Outcome:**
- Negative RT-PCR result on Day 6: 24% in IVM arm vs. 32% in placebo arm (rate ratio 0.8; P = 0.348)

**Secondary Outcomes:**
- Symptom resolution by Day 6: 84% in IVM arm vs. 90% in placebo arm (rate ratio 0.9; P = 0.36)
- Discharge by Day 10: 80% in IVM arm vs. 74% in placebo arm (rate ratio 1.1; P = 0.43)
- Need for ICU admission or MV: no difference between arms
- In-hospital mortality: 0 in IVM arm (0%) vs. 4 in placebo arm (7%)

## Limitations and Interpretation

**Key Limitations:**
- Although the primary endpoint was a negative SARS-CoV-2 RT-PCR result on Day 6, no RT-PCR result or an inconclusive RT-PCR result was reported for 42% of patients in the IVM arm and 23% in the placebo arm.
- The time to discharge was not reported, and outcomes after discharge were not evaluated.

**Interpretation:**
- IVM provided no significant virologic or clinical benefit for patients with mild to moderate COVID-19.
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<tbody>
<tr>
<td><strong>RIVET-COV:</strong> Double-Blind, Placebo-Controlled, Randomized Trial of Ivermectin in Patients With Mild to Moderate COVID-19 in India</td>
<td><strong>Participant Characteristics:</strong>&lt;br&gt;• Mean age 35 years; 89% men&lt;br&gt;• 60% to 68% with mild COVID-19 (including asymptomatic patients); 33% to 40% with moderate COVID-19&lt;br&gt;• Median duration of symptoms: 4–5 days, similar across arms&lt;br&gt;• 10% received concurrent antivirals (RDV, favipiravir, or HCQ); no difference across arms</td>
<td><strong>Key Limitation:</strong>&lt;br&gt;• Small sample size&lt;br&gt;&lt;br&gt;<strong>Interpretation:</strong>&lt;br&gt;• For patients who received IVM and those who received placebo, there was no difference in the proportion of negative RT-PCR results at Day 5 or clinical outcomes.</td>
</tr>
<tr>
<td><strong>Key Inclusion Criteria:</strong>&lt;br&gt;• Positive SARS-CoV-2 RT-PCR or antigen test result&lt;br&gt;• Nonsevere COVID-19</td>
<td><strong>Primary Outcomes:</strong>&lt;br&gt;• Negative RT-PCR result at Day 5: 48% in IVM 24 mg arm vs. 35% in IVM 12 mg arm vs. 31% in placebo arm (P = 0.30)&lt;br&gt;• Decline of VL at Day 5: no significant difference between arms</td>
<td><strong>Key Secondary Endpoints:</strong>&lt;br&gt;• Time to symptom resolution: no difference between arms&lt;br&gt;• Clinical worsening at Day 14: 8% in IVM 24 mg arm vs. 5% in IVM 12 mg arm vs. 11% in placebo arm (P = 0.65)&lt;br&gt;• Number of hospital-free days at Day 28: no difference between arms&lt;br&gt;• Frequency of AEs: no difference between arms; no SAEs</td>
</tr>
<tr>
<td><strong>Key Exclusion Criteria:</strong>&lt;br&gt;• CrCl &lt;30 mL/min&lt;br&gt;• Transaminases &gt;5 times ULN&lt;br&gt;• MI, heart failure, QTc interval prolongation&lt;br&gt;• Severe comorbidity</td>
<td><strong>Secondary Outcomes:</strong>&lt;br&gt;• Time to symptom resolution: no difference between arms</td>
<td><strong>Interventions:</strong>&lt;br&gt;• Single dose of IVM 24 mg PO (n = 51)&lt;br&gt;• Single dose of IVM 12 mg PO (n = 49)&lt;br&gt;• Placebo (n = 52)</td>
</tr>
<tr>
<td><strong>Interventions:</strong>&lt;br&gt;• Single dose of IVM 24 mg PO (n = 51)&lt;br&gt;• Single dose of IVM 12 mg PO (n = 49)&lt;br&gt;• Placebo (n = 52)</td>
<td><strong>Secondary Outcomes:</strong>&lt;br&gt;• Time to symptom resolution: no difference between arms</td>
<td><strong>Participant Characteristics:</strong>&lt;br&gt;• Mean age 35 years; 89% men&lt;br&gt;• 60% to 68% with mild COVID-19 (including asymptomatic patients); 33% to 40% with moderate COVID-19&lt;br&gt;• Median duration of symptoms: 4–5 days, similar across arms&lt;br&gt;• 10% received concurrent antivirals (RDV, favipiravir, or HCQ); no difference across arms</td>
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<td>Results</td>
<td>Limitations and Interpretation</td>
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</table>
| **COVER:** Phase 2, Double-Blind RCT of Ivermectin in Nonhospitalized Patients With COVID-19 in Italy[^4]  

**Key Inclusion Criteria:**  
- Asymptomatic or oligosymptomatic disease  
- SARS-CoV-2 infection confirmed by RT-PCR result  
- Not hospitalized or receiving supplemental oxygen  

**Key Exclusion Criteria:**  
- CNS disease  
- Receiving dialysis  
- Severe medical condition with <6 months survival prognosis  
- Use of warfarin, antiviral agents, CQ, or HCQ  

**Interventions:**  
- IVM 1,200 μg/kg PO once daily for 5 days (n = 32)  
- IVM 600 μg/kg plus placebo PO once daily for 5 days (n = 29)  
- Placebo PO (n = 32)  

**Primary Endpoints:**  
- Number of SAEs  
- Change in VL at Day 7  

**Participant Characteristics:**  
- Median age 47 years; 58% men  
- 86% with symptoms  

**Primary Outcomes:**  
- Number of SAEs: 0  
- Mean log₁₀ reduction in VL at Day 7: 2.9 in IVM 1,200 μg/kg arm vs. 2.5 in IVM 600 μg/kg arm vs. 2.0 in placebo arm (IVM 1,200 μg/kg vs. placebo,  \( P = 0.099 \); IVM 600 μg/kg vs. placebo,  \( P = 0.122 \))  

**AE Outcomes:**  
- 14 (15.1%) discontinued treatment: 11 (34.4%) in IVM 1,200 μg/kg arm vs. 2 (6.9%) in IVM 600 μg/kg arm vs. 1 (3.1%) in placebo arm  
- All discontinuations in IVM 1,200 μg/kg arm due to tolerability  

**Key Limitations:**  
- Small, Phase 2 study  
- 90% of subjects screened were not enrolled for various reasons.  
- Recruitment stopped early because of decline in the number of COVID-19 cases.  

**Interpretations:**  
- A high dose of IVM (1,200 μg/kg) appears to be safe but not well-tolerated; 34% discontinued therapy due to AEs.  
- There was no significant difference in reduction of VL between IVM and placebo arms.
### Methods

**Double-Blind RCT of Ivermectin, Chloroquine, or Hydroxychloroquine in Hospitalized Adults With Severe COVID-19 in Brazil**

**Key Inclusion Criteria:**
- Hospitalized with laboratory-confirmed SARS-CoV-2 infection
- ≥1 of the following severity criteria:
  - Dyspnea
  - Tachypnea (>30 breaths/min)
  - SpO₂ <93%
  - PaO₂/FiO₂ <300 mm Hg
  - Involvement of >50% of lungs by CXR or CT

**Key Exclusion Criterion:**
- Cardiac arrhythmia

**Interventions:**
- IVM 14 mg once daily for 3 days (n = 53)
- CQ 450 mg twice daily on Day 0, then once daily for 4 days (n = 61)
- HCQ 400 mg twice daily on Day 0, then once daily for 4 days (n = 54)

**Endpoints:**
- Need for supplemental oxygen, MV, or ICU admission
- Occurrence of AEs
- Mortality

**Participant Characteristics:**
- Mean age 53 years; 58% men
- Most common comorbidities: 43% with HTN; 28% with DM; 38% with BMI >30
- 76% with respiratory failure on admission

### Results

**Outcomes:**
- No difference between IVM, CQ, and HCQ arms in:
  - Need for supplemental oxygen: 88% vs. 89% vs. 90%
  - ICU admission: 28% vs. 22% vs. 21%
  - Need for MV: 24% vs. 21% vs. 21%
  - Mortality: 23% vs. 21% vs. 22%
  - Mean number of days of supplemental oxygen: 8 days for each arm
  - Occurrence of AEs: no difference between arms
  - Baseline characteristics significantly associated with mortality:
    - Aged >60 years (HR 2.4)
    - DM (HR 1.9)
    - BMI >33 (HR 2.0)
    - SpO₂ <90% (HR 5.8)

### Limitations and Interpretation

**Key Limitations:**
- Small sample size
- No clearly defined primary endpoint

**Interpretation:**
- Compared to CQ or HCQ, IVM did not reduce the proportion of hospitalized patients with severe COVID-19 who died or who required supplemental oxygen, ICU admission, or MV.

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**Key:** AE = adverse event; ALT = alanine aminotransferase; BMI = body mass index; CNS = central nervous system; CQ = chloroquine; CrCl = creatinine clearance; CT = computed tomography; CXR = chest X-ray; DM = diabetes mellitus; HCQ = hydroxychloroquine; HTN = hypertension; ICU = intensive care unit; ITT = intention-to-treat; IVM = ivermectin; LOS = length of stay; MI = myocardial infarction; mITT = modified intention-to-treat; MV = mechanical ventilation; the Panel = the COVID-19 Treatment Guidelines Panel; PaO₂/FiO₂ = ratio of arterial partial pressure of oxygen to fraction of inspired oxygen; PO = orally; RCT = randomized controlled trial; RDV = remdesivir; RT-PCR = reverse transcriptase polymerase chain reaction; SAE = severe adverse event; SOC = standard of care; SpO₂ = oxygen saturation; ULN = upper limit of normal; VL = viral load
References


