



Table 4c. Ivermectin: Selected Clinical Data

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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-19.¹⁻²⁶ However, those studies have limitations that make them less definitive and informative than the studies summarized in the table.

Methods	Results	Limitations and Interpretation
TOGETHER: Double-Blind, Adaptive, RCT of Ivermectin in Nonhospitalized Patients With COVID-19 in Brazil²⁷		
<p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • 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) <p>Interventions:</p> <ul style="list-style-type: none"> • IVM 400 µg/kg PO per day for 3 days (n = 679) • Placebo (n = 679; not all participants received IVM placebo) <p>Primary Endpoint:</p> <ul style="list-style-type: none"> • Composite of emergency setting observation >6 hours or hospitalized for COVID-19 within 28 days of randomization <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • Viral clearance at Day 7 • All-cause mortality • Occurrence of AEs 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • 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 <p>Primary Outcome:</p> <ul style="list-style-type: none"> • 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) <ul style="list-style-type: none"> • 171 (81%) of all events were hospitalizations (ITT) <p>Secondary Outcomes:</p> <ul style="list-style-type: none"> • No difference between IVM and placebo arms in: <ul style="list-style-type: none"> • 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 	<p>Key Limitations:</p> <ul style="list-style-type: none"> • 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. <p>Interpretation:</p> <ul style="list-style-type: none"> • In outpatients with recent COVID-19 infection, IVM did not reduce the need for emergency setting visits or hospitalization when compared with placebo.

Methods	Results	Limitations and Interpretation
IVERCOR-COVID19: Double-Blind, Placebo-Controlled, Randomized Trial of Ivermectin in Nonhospitalized Patients With COVID-19 in Argentina²⁸		
<p>Key Inclusion Criterion:</p> <ul style="list-style-type: none"> • Positive SARS-CoV-2 RT-PCR result within 48 hours of screening <p>Key Exclusion Criteria:</p> <ul style="list-style-type: none"> • Oxygen supplementation or hospitalization • Concomitant use of CQ or HCQ <p>Interventions:</p> <ul style="list-style-type: none"> • Weight-based dose of IVM PO at enrollment and 24 hours later for a maximum total dose of 48 mg (n = 250) • Placebo (n = 251) <p>Primary Endpoint:</p> <ul style="list-style-type: none"> • Hospitalization for any reason <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • Need for MV • All-cause mortality • Occurrence of AEs 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • Mean age 42 years; 8% aged ≥ 65 years; 47% women • 24% with HTN; 10% with DM; 58% with ≥ 1 comorbidity • Median time from symptom onset: 4 days <p>Primary Outcome:</p> <ul style="list-style-type: none"> • Hospitalization for any reason: 5.6% in IVM arm vs. 8.3% in placebo arm (OR 0.65; 95% CI, 0.32–1.31; $P = 0.23$) <p>Secondary Outcomes:</p> <ul style="list-style-type: none"> • Need for MV: 2% in IVM arm vs. 1% in placebo arm ($P = 0.7$) • All-cause mortality: 2% in IVM arm vs. 1% in placebo arm ($P = 0.7$) • Occurrence of AEs: 18% in IVM arm vs. 21% in placebo arm ($P = 0.6$) 	<p>Key Limitation:</p> <ul style="list-style-type: none"> • Enrolled a fairly young population with few of the comorbidities that predict disease progression. <p>Interpretation:</p> <ul style="list-style-type: none"> • Among patients who had recently acquired SARS-CoV-2 infection, there was no evidence that IVM provided any clinical benefit.

Methods	Results	Limitations and Interpretation
I-TECH: Open-Label RCT of Ivermectin in Patients With Mild to Moderate COVID-19 in Malaysia²⁹		
<p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • Positive SARS-CoV-2 RT-PCR or antigen test result within 7 days of symptom onset • Aged ≥ 50 years • ≥ 1 comorbidity <p>Key Exclusion Criteria:</p> <ul style="list-style-type: none"> • Required supplemental oxygen • Severe hepatic impairment (ALT >10 times the ULN) <p>Interventions:</p> <ul style="list-style-type: none"> • IVM: 400 $\mu\text{g}/\text{kg}$ PO daily for 5 days plus SOC (n = 241) • SOC (n = 249) <p>Primary Endpoint:</p> <ul style="list-style-type: none"> • Progression to severe COVID-19 (i.e., hypoxia requiring supplemental oxygen to maintain $\text{SpO}_2 \geq 95\%$) <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • In-hospital, all-cause mortality by Day 28 • MV or ICU admission • Occurrence of AEs 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • Mean age 63 years; 55% women • 68% received ≥ 1 dose COVID-19 vaccine; 52% received 2 doses • Most common comorbidities: 75% with HTN; 54% with DM; 24% with dyslipidemia • Mean duration of symptoms: 5 days <p>Primary Outcome:</p> <ul style="list-style-type: none"> • 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; $P = 0.25$) <p>Secondary Outcomes:</p> <ul style="list-style-type: none"> • No difference between IVM plus SOC arm and SOC alone arm in: <ul style="list-style-type: none"> • 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) 	<p>Key Limitation:</p> <ul style="list-style-type: none"> • Open-label study <p>Interpretation:</p> <ul style="list-style-type: none"> • In patients with mild to moderate COVID-19, there was no evidence that IVM provided any clinical benefit, including no evidence that IVM reduced progression to severe disease.

Methods	Results	Limitations and Interpretation
Double-Blind, Placebo-Controlled, Randomized Trial of Ivermectin in Patients With Mild COVID-19 in Colombia ³⁰		
<p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • Positive SARS-CoV-2 RT-PCR or antigen test result • Symptoms \leq 7 days • Mild disease <p>Key Exclusion Criteria:</p> <ul style="list-style-type: none"> • Asymptomatic disease • Severe pneumonia • Hepatic dysfunction <p>Interventions:</p> <ul style="list-style-type: none"> • IVM 300 μg/kg PO per day for 5 days (n = 200) • Placebo PO (n = 198) <p>Primary Endpoint:</p> <ul style="list-style-type: none"> • Time to resolution of symptoms within 21 days <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • Clinical deterioration • Escalation of care • Occurrence of AEs 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • Median age 37 years; 4% aged \geq65 years in IVM arm, 8% in placebo arm; 39% men in IVM arm, 45% in placebo arm • 79% with no known comorbidities • Median symptom onset to randomization: 5 days <p>Primary Outcome:</p> <ul style="list-style-type: none"> • Median time to symptom resolution: 10 days in IVM arm vs. 12 days in placebo arm (HR 1.07; $P = 0.53$) <ul style="list-style-type: none"> • Symptoms resolved by Day 21: 82% in IVM arm vs. 79% in placebo arm <p>Secondary Outcomes:</p> <ul style="list-style-type: none"> • Clinical deterioration: no difference between arms • Escalation of care: no difference between arms • Occurrence of AEs: <ul style="list-style-type: none"> • Discontinued treatment due to AEs: 8% in IVM arm vs. 3% in placebo arm • No SAEs were related to intervention 	<p>Key Limitations:</p> <ul style="list-style-type: none"> • 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. • The study enrolled younger, healthier patients, a population that does not typically develop severe COVID-19. <p>Interpretation:</p> <ul style="list-style-type: none"> • In patients with mild COVID-19, IVM 300 μg/kg per day for 5 days did not improve the time to resolution of symptoms.

Methods	Results	Limitations and Interpretation
Open-Label RCT of Ivermectin in Hospitalized Patients With COVID-19 in Egypt ³¹		
<p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • RT-PCR-confirmed SARS-CoV-2 infection by pharyngeal swab • Hospitalized with mild to moderate COVID-19 <p>Key Exclusion Criterion:</p> <ul style="list-style-type: none"> • Cardiac problems <p>Interventions:</p> <ul style="list-style-type: none"> • IVM 12 mg PO once daily for 3 days (n = 82) • SOC (n = 82) <p>Primary Endpoint:</p> <ul style="list-style-type: none"> • All-cause mortality by 28 days <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • Hospital LOS • Need for MV 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • Mean age 42 years for IVM arm, 39 years for SOC arm; 50% men • 49% with ≥1 comorbidity <p>Primary Outcome:</p> <ul style="list-style-type: none"> • All-cause mortality by 28 days: 3 (3.7%) in IVM arm vs. 4 (4.9%) in SOC arm (<i>P</i> = 1.00) <p>Secondary Outcomes:</p> <ul style="list-style-type: none"> • Mean hospital LOS: 9 days in IVM arm vs. 11 days in SOC arm (<i>P</i> = 0.085) • Need for MV: 3 (3.7%) in each arm (<i>P</i> = 1.00) 	<p>Key Limitation:</p> <ul style="list-style-type: none"> • Small, open-label study <p>Interpretation:</p> <ul style="list-style-type: none"> • Use of IVM, when compared with the SOC, did not result in differences in all-cause mortality, hospital LOS, or the need for MV.

Methods	Results	Limitations and Interpretation
Double-Blind, Placebo-Controlled, Randomized Trial of Ivermectin in Patients With Mild to Moderate COVID-19 in India ³²		
<p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • Positive SARS-CoV-2 RT-PCR or antigen test result • Hospitalized with mild or moderate COVID-19 <p>Interventions:</p> <ul style="list-style-type: none"> • IVM 12 mg PO for 2 days (n = 55) • Placebo PO (n = 57) <p>Primary Endpoint:</p> <ul style="list-style-type: none"> • Negative SARS-CoV-2 RT-PCR result on Day 6 <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • Symptom resolution by Day 6 • Discharge by Day 10 • Need for ICU admission or MV • In-hospital mortality 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • 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 <p>Primary Outcome:</p> <ul style="list-style-type: none"> • Negative RT-PCR result on Day 6: 24% in IVM arm vs. 32% in placebo arm (rate ratio 0.8; <i>P</i> = 0.348) <p>Secondary Outcomes:</p> <ul style="list-style-type: none"> • Symptom resolution by Day 6: 84% in IVM arm vs. 90% in placebo arm (rate ratio 0.9; <i>P</i> = 0.36) • Discharge by Day 10: 80% in IVM arm vs. 74% in placebo arm (rate ratio 1.1; <i>P</i> = 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%) 	<p>Key Limitations:</p> <ul style="list-style-type: none"> • 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. <p>Interpretation:</p> <ul style="list-style-type: none"> • IVM provided no significant virologic or clinical benefit for patients with mild to moderate COVID-19.

Methods	Results	Limitations and Interpretation
RIVET-COV: Double-Blind, Placebo-Controlled, Randomized Trial of Ivermectin in Patients With Mild to Moderate COVID-19 in India³³		
<p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • Positive SARS-CoV-2 RT-PCR or antigen test result • Nonsevere COVID-19 <p>Key Exclusion Criteria:</p> <ul style="list-style-type: none"> • CrCl <30 mL/min • Transaminases >5 times ULN • MI, heart failure, QTc interval prolongation • Severe comorbidity <p>Interventions:</p> <ul style="list-style-type: none"> • Single dose of IVM 24 mg PO (n = 51) • Single dose of IVM 12 mg PO (n = 49) • Placebo (n = 52) <p>Primary Endpoints:</p> <ul style="list-style-type: none"> • Negative RT-PCR result at Day 5 • Decline of VL at Day 5 <p>Key Secondary Endpoints:</p> <ul style="list-style-type: none"> • Time to symptom resolution • Clinical worsening at Day 14 • Number of hospital-free days at Day 28 • Frequency of AEs 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • Mean age 35 years; 89% men • 60% to 68% with mild COVID-19 (including asymptomatic patients); 33% to 40% with moderate COVID-19 • Median duration of symptoms: 4–5 days, similar across arms • 10% received concurrent antivirals (RDV, favipiravir, or HCQ); no difference across arms <p>Primary Outcomes:</p> <ul style="list-style-type: none"> • 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 ($P = 0.30$) • Decline of VL at Day 5: no significant difference between arms <p>Secondary Outcomes:</p> <ul style="list-style-type: none"> • Time to symptom resolution: no difference between arms • Clinical worsening at Day 14: 8% in IVM 24 mg arm vs. 5% in IVM 12 mg arm vs. 11% in placebo arm ($P = 0.65$) • Number of hospital-free days at Day 28: no difference between arms • Frequency of AEs: no difference between arms; no SAEs 	<p>Key Limitation:</p> <ul style="list-style-type: none"> • Small sample size <p>Interpretation:</p> <ul style="list-style-type: none"> • 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.

Methods	Results	Limitations and Interpretation
COVER: Phase 2, Double-Blind RCT of Ivermectin in Nonhospitalized Patients With COVID-19 in Italy³⁴		
<p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • Asymptomatic or oligosymptomatic disease • SARS-CoV-2 infection confirmed by RT-PCR result • Not hospitalized or receiving supplemental oxygen <p>Key Exclusion Criteria:</p> <ul style="list-style-type: none"> • CNS disease • Receiving dialysis • Severe medical condition with <6 months survival prognosis • Use of warfarin, antiviral agents, CQ, or HCQ <p>Interventions:</p> <ul style="list-style-type: none"> • 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) <p>Primary Endpoints:</p> <ul style="list-style-type: none"> • Number of SAEs • Change in VL at Day 7 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • Median age 47 years; 58% men • 86% with symptoms <p>Primary Outcomes:</p> <ul style="list-style-type: none"> • 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, <i>P</i> = 0.099; IVM 600 µg/kg vs. placebo, <i>P</i> = 0.122) <p>AE Outcomes:</p> <ul style="list-style-type: none"> • 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 	<p>Key Limitations:</p> <ul style="list-style-type: none"> • 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. <p>Interpretations:</p> <ul style="list-style-type: none"> • 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	Results	Limitations and Interpretation
Double-Blind RCT of Ivermectin, Chloroquine, or Hydroxychloroquine in Hospitalized Adults With Severe COVID-19 in Brazil ³⁵		
<p>Key Inclusion Criteria:</p> <ul style="list-style-type: none"> • Hospitalized with laboratory-confirmed SARS-CoV-2 infection • ≥1 of the following severity criteria: <ul style="list-style-type: none"> • Dyspnea • Tachypnea (>30 breaths/min) • SpO₂ <93% • PaO₂/FiO₂ <300 mm Hg • Involvement of >50% of lungs by CXR or CT <p>Key Exclusion Criterion:</p> <ul style="list-style-type: none"> • Cardiac arrhythmia <p>Interventions:</p> <ul style="list-style-type: none"> • 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) <p>Endpoints:</p> <ul style="list-style-type: none"> • Need for supplemental oxygen, MV, or ICU admission • Occurrence of AEs • Mortality 	<p>Participant Characteristics:</p> <ul style="list-style-type: none"> • 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 <p>Outcomes:</p> <ul style="list-style-type: none"> • No difference between IVM, CQ, and HCQ arms in: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • Aged >60 years (HR 2.4) • DM (HR 1.9) • BMI >33 (HR 2.0) • SpO₂ <90% (HR 5.8) 	<p>Key Limitations:</p> <ul style="list-style-type: none"> • Small sample size • No clearly defined primary endpoint <p>Interpretation:</p> <ul style="list-style-type: none"> • 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.

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

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