

Title: **Infliximab for Treatment of Adults Hospitalized with Moderate or Severe Covid-19.**

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Abstract:

Background: Immune dysregulation contributes to poorer outcomes in severe Covid-19. Immunomodulators targeting various pathways have improved outcomes. We investigated whether infliximab provides benefit over standard of care.

Methods: We conducted a master protocol investigating immunomodulators for potential benefit in treatment of participants hospitalized with Covid-19 pneumonia. We report results for infliximab (single dose infusion) versus shared placebo both with standard of care. Primary outcome was time to recovery by day 29 (28 days after randomization). Key secondary endpoints included 14-day clinical status and 28-day mortality.

Results: A total of 1033 participants received study drug (517 infliximab, 516 placebo). Mean age was 54.8 years, 60.3% were male, 48.6% Hispanic or Latino, and 14% Black. No statistically significant difference in the primary endpoint was seen with infliximab compared with placebo (recovery rate ratio 1.13, 95% CI 0.99-1.29; p=0.063). Median (IQR) time to recovery was 8 days (7, 9) for infliximab and 9 days (8, 10) for placebo. Participants assigned to infliximab were more likely to have an improved clinical status at day 14 (OR 1.32, 95% CI 1.05-1.66). Twenty-eight-day mortality was 10.1% with infliximab versus 14.5% with placebo, with 41% lower odds of dying in those receiving infliximab (OR 0.59, 95% CI 0.39-0.90). No differences in risk of serious adverse events including secondary infections.

Conclusions: Infliximab did not demonstrate statistically significant improvement in time to recovery. It was associated with improved 14-day clinical status and substantial reduction in 28-day mortality compared with standard of care.

Trial registration: ClinicalTrials.gov (NCT04593940).

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