Overview of Study Documents

A Multicenter, Adaptive, Randomized, Blinded Controlled Trial of the Safety and Efficacy of Investigational Therapeutics for Hospitalized Patients with Acute Respiratory Distress Syndrome Associated with COVID-19

05 August 2025

NCT06729606

(Master protocol: NCT04843761)

ACTIV-3b: Therapeutics for Severely Ill Inpatients With COVID-19 (TESICO) trial.

Overview of Trial Documents

Master protocol: NCT04843761
Aviptadil Substudy (H1): NCT06729606
Remdesivir Substudy (H2): NCT06729593

Document	Document Date	Description
Study Protocol: Master	March 8, 2022	The master protocol document for TESICO/ACTIV-3b. This document should be used together with the agent specific appendices (H1 and H2) to understand the data collection for the Aviptadil and Remdesvir substudies.
Study Protocol: Aviptadil (H1)	March 8, 2022	Appendix H1 to the TESICO master protocol document. Provides additional agent-specific information for the Aviptadil component of the trial.
Study Protocol: Remdesivir (H2)	April 1, 2021	Appendix H2 to the TESICO master protocol document. Provides additional agent-specific information for the Remdesivir component of the trial and a description of the 4 randomization strata used for enrollment into both agents.
Statistical Analysis Plan: Main	August 5, 2021	This document applies for both the Aviptadil and Remdesivir substudies.
Statistical Analysis Plan: Addendum	May 1, 2022	This document applies to the Aviptadil substudy.
Informed Consent	March 8, 2022	This document applies for both the Aviptadil and Remdesivir substudies.