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June 21, 2021

ACTIV-4A is a trial investigating whether anti-platelet therapy with P2Y12 inhibitors added to standard of care versus standard of care alone improves outcome for patients hospitalized with COVID-19. Standard of care for moderately ill hospitalized patients includes therapeutic dose heparin, and for severe state patients includes prophylactic dose heparin.

The CONNECTS ACTIV DSMB met on June 16, 2021. Based on review of data from ACTIV-4A, the DSMB has recommended and NHLBI agreed that enrollment and study prescribed treatment of patients who meet the criteria for the moderate state (non-ICU level of care) should be stopped due to meeting the predetermined criteria of futility for adding the P2Y12 inhibitor to standard of care. Participants will continued to be followed as planned.

The trial will continue to enroll patients with severe illness (requiring ICU level of care) to see if anti-platelet therapy with P2Y12 inhibitors added to standard of care versus standard of care alone improves outcome.

As is normal for clinical trials, ACTIV-4A is overseen by an independent board that routinely reviews the data. The CONNECTS ACTIV-4 board is composed of experts in ethics, biostatistics, clinical trials, and blood clotting disorders. Informed by the deliberations of the oversight board, all the trial sites have stopped enrollment of moderately ill patients.

ACTIV-4A trial is led by the University of Pittsburgh and New York University Grossman School of Medicine and is funded by the NHLBI.