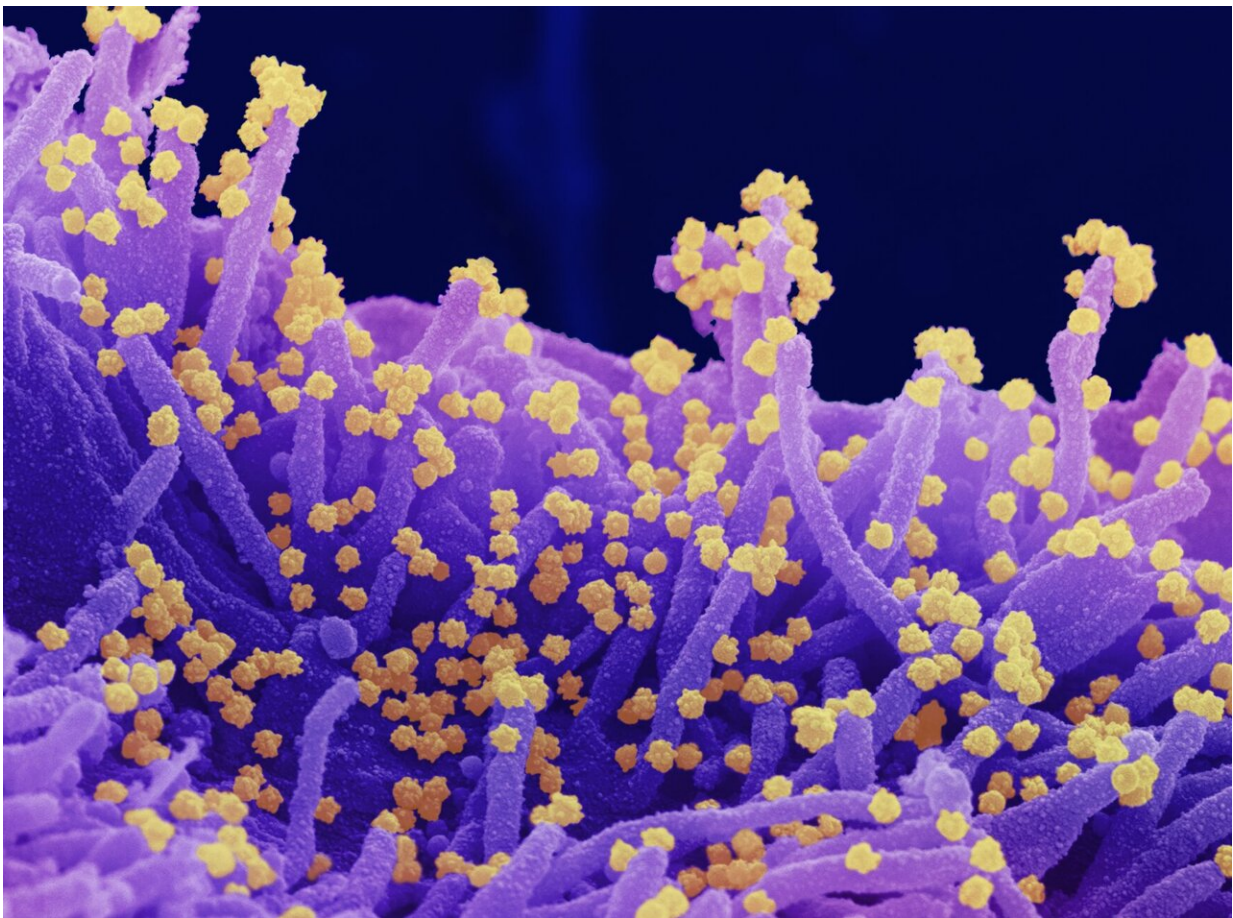


Hyperimmune intravenous immunoglobulin does not improve outcomes for adults hospitalized with COVID-19

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Scanning electron microscope image of SARS-CoV-2 (round gold particles) emerging from the surface of a cell cultured in the lab. Image captured and colorized at Rocky Mountain Laboratories in Hamilton, Montana. Credit: NIAID

A clinical trial has found that the combination of remdesivir plus a highly concentrated solution of antibodies that neutralize SARS-CoV-2, the virus that causes COVID-19, is not more effective than remdesivir alone for treating adults hospitalized with the disease. The trial also found that the safety of this experimental treatment may vary depending on whether a person naturally generates SARS-CoV-2-neutralizing antibodies before receiving it. The results of the multinational Phase 3 trial were published today in the journal *The Lancet*.

The National Institute of Allergy and Infectious Diseases (NIAID), part of the National Institutes of Health, sponsored and funded the trial, called Inpatient Treatment with Anti-Coronavirus Immunoglobulin, or ITAC. The trial was conducted by the NIAID-funded International Network for Strategic Initiatives in Global HIV Trials (INSIGHT). Mark Polizzotto, M.D., Ph.D., head of the Clinical Hub for Interventional Research at the College of Health & Medicine of The Australian National University in Canberra, led the trial.

The antibody solution tested in the ITAC trial was anti-coronavirus hyperimmune intravenous immunoglobulin, or hIVIG. The antibodies in anti-coronavirus hIVIG came from the liquid portion of blood, or plasma, donated by healthy people who had recovered from COVID-19. These antibodies were highly purified and concentrated so that the anti-coronavirus hIVIG consistently contained several times more SARS-CoV-2 neutralizing antibodies than typically found in the plasma of people who have recovered from COVID-19.

"In our quest to find safe and effective treatments for COVID-19, we had hoped that adding anti-coronavirus hIVIG to a [remdesivir](#) regimen would give the immune system a boost to help suppress the virus early in the course of hospitalization," said NIAID Director Anthony S. Fauci, M.D. "Unfortunately, the ITAC trial demonstrated that this strategy did not improve the health of adults hospitalized with COVID-19 and may

be harmful for a certain subset of patients. Studies testing this strategy in non-hospitalized adults earlier in the course of infection are underway."

Four companies collaborated to provide anti-coronavirus hIVIG for the trial: Emergent BioSolutions of Gaithersburg, Maryland; Grifols S.A. of Barcelona; CSL Behring of King of Prussia, Pennsylvania; and Takeda of Tokyo.

Remdesivir is a broad-spectrum antiviral currently approved by the U.S. Food and Drug Administration and recommended for treating certain patients with COVID-19 based on data from several randomized [clinical trials](#), including the NIAID-sponsored [Adaptive COVID-19 Treatment Trial \(ACTT-1\)](#). FDA granted the approval to Gilead Sciences, Inc. of Foster City, California.

The ITAC study team enrolled nearly 600 hospitalized adults aged 18 years or older who had COVID-19 symptoms for up to 12 days and did not have life-threatening organ dysfunction or organ failure. Enrollment took place at 63 sites in 11 countries in Africa, Asia, Europe, North America and South America between October 2020 and February 2021. Study participants were assigned at random to receive infusions of either anti-coronavirus hIVIG and remdesivir or a placebo and remdesivir. Neither the participants nor the study team, except for pharmacists who prepared the infusions, knew who received which treatment regimen until the end of the trial. All participants also received supportive care reflecting local practice and national guidelines.

The main goal of the trial was to compare the health status of participants seven days after beginning treatment with hIVIG plus remdesivir with that of participants seven days after beginning treatment with remdesivir alone. The primary endpoint was an ordinal outcome with seven mutually exclusive categories ranging from no limiting symptoms due to COVID-19, to death. Safety was assessed at day seven

with a composite outcome that included death, serious adverse events including organ failure and serious infections, and severe events that made performing basic functions impossible.

The ITAC investigators found that participants who received hIVIG plus remdesivir did not have better health status seven days after beginning treatment compared with participants who received remdesivir alone. Similarly, participants who received hIVIG plus remdesivir had no improvement in other clinical outcomes during the 28-day follow-up period compared to those who received remdesivir alone.

The investigators also found no overall difference in safety at day seven for people who received hIVIG plus remdesivir compared to those who received remdesivir alone. However, the researchers additionally undertook a pre-specified subgroup analysis of safety among participants who had developed SARS-CoV-2 neutralizing antibodies before receiving hIVIG. In this group, the odds of a worse safety outcome at day seven were 1.6 times as high for people who received hIVIG as for those who did not. Further research is needed to understand why. The difference was no longer apparent at day 28.

The ITAC trial was associated with the [Accelerating COVID-19 Therapeutic Interventions and Vaccines \(ACTIV\)](#) public-private partnership. Further information about the trial is available in [this NIAID press release](#) and at [ClinicalTrials.gov](#) under study identifier [NCT04546581](#).

Reference: MN Polizzotto *et al.* Hyperimmune immunoglobulin for hospitalised patients with COVID-19 (ITAC): a double-blind, placebo-controlled, phase 3, randomised trial. *The Lancet* [DOI: 10.1016/S0140-6736\(22\)00101-5](#) (2022).

More information: Hyperimmune immunoglobulin for hospitalised

patients with COVID-19 (ITAC): a double-blind, placebo-controlled, phase 3, randomised trial, *The Lancet* (2022). [DOI: 10.1016/S0140-6736\(22\)00101-5](https://doi.org/10.1016/S0140-6736(22)00101-5)

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