



Trial Summary for [combatcovid.hhs.gov](https://combatcovid.hhs.gov)

## **OTAC: Outpatient Treatment with Anti-Coronavirus Immunoglobulin**

### ***About this trial***

People early on in their infection who test positive for COVID-19 and have a higher risk of getting very sick will take part in this study. The study team hopes to find out if giving anti-SARS-CoV-2 hyperimmunoglobulin (hIVIG) to people early in their infection with COVID-19, before the body has had a chance to make its own antibodies, can help prevent bad effects from COVID-19 and enable them to stay out of the hospital. If you join this study, you will receive either study drug, hIVIG, or placebo given through a vein in the arm as a single dose. You will also get the usual treatment and care for COVID-19 according to local guidelines. The study lasts 28 days with some of the scheduled study visits taking place over the phone.

### ***What treatment is being tested in this trial?***

COVID-19 disease is caused by infection with the SARS-CoV-2 virus. Anti-SARS-CoV-2 hyperimmune intravenous immunoglobulin (hIVIG) is made by combining and concentrating antibodies from different healthy people who have recovered from COVID-19. The anti-SARS-CoV-2 antibodies bind to the virus and keep it from entering into cells. It is also different from “convalescent plasma” from a single person in that hIVIG consistently provides a high level of antibodies. In the lab, it has been shown to work better against “variant” (i.e., “mutated” or changed) forms of the SARS-CoV-2 virus than single or combination antibody treatments. Variant forms of the virus have become widespread in different parts of the world.

### ***What is the type of clinical trial being conducted?***

Randomized, double-blind, placebo-controlled trial. Participants will have a 50-50 chance (like tossing a coin) of being assigned to the “active” study drug, hIVIG, or placebo (salt water with no study drug).

### **For more information:**

Call Infusion Associates’ clinical research nurse, Mary Beth Readwin at (616) 655-1909.