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<https://www.wsj.com/articles/drug-derived-from-plasma-of-covid-19-patients-to-be-tested-as-preventive-measure-11594211400>

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# Drug Derived From Plasma of Covid-19 Patients to Be Tested as Preventive Measure

Mount Sinai Health System is working with drugmaker Emergent Biosolutions on drug that could protect health-care workers and others



A recovered coronavirus patient in Indonesia donated blood samples last month so the plasma could be used for critically ill patients.

PHOTO: FULLY HANDOKO/SHUTTERSTOCK

By [Amy Dockser Marcus](#)

July 8, 2020 8:30 am ET

Drugmaker [Emergent Biosolutions Inc.](#) [EBS +4.68% ▲](#) plans to work with Mount Sinai Health System in New York City to test whether a drug derived from the blood plasma of recovered Covid-19 patients can prevent infections in doctors, nurses and military forces.

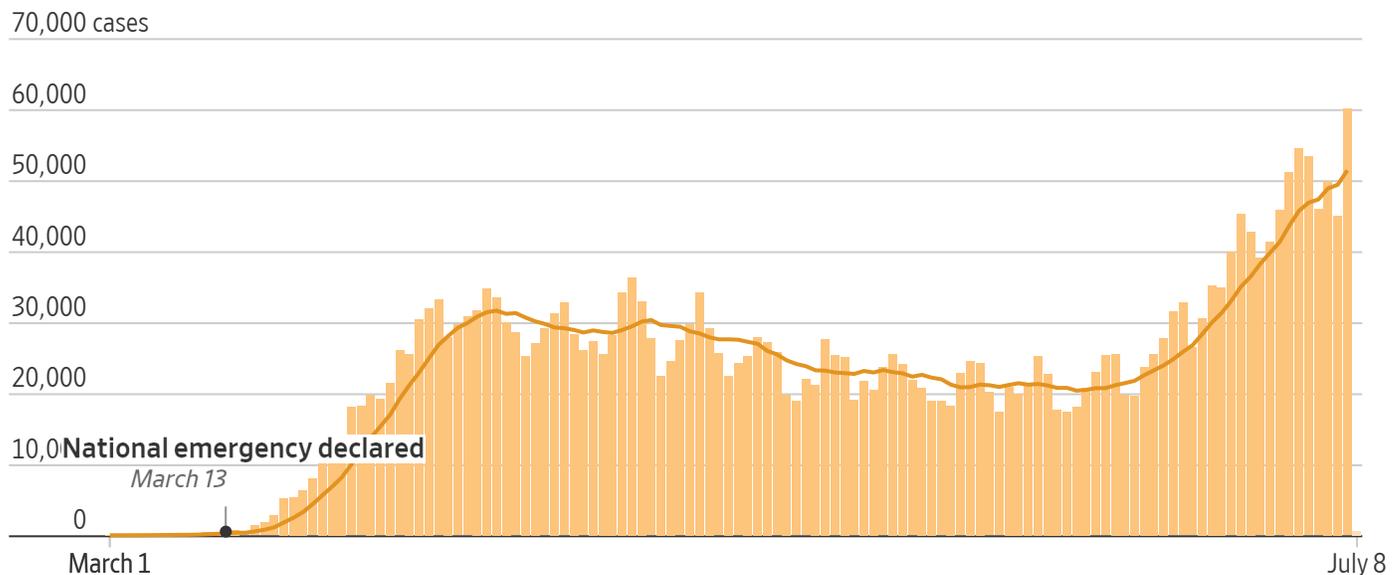
The proposed study, which the partners said they would announce Wednesday, would add to efforts evaluating the coronavirus-fighting potential of experimental drugs made from plasma donated by recovered patients.

If the drug proves to work safely, it could help protect health-care workers and other people working in essential jobs who are at high risk of infection until a vaccine is ready and perhaps even after.

Some people don't tolerate vaccines, said Judith Aberg, chief of the division of infectious diseases and immunology at Mount Sinai. "This offers another avenue of prevention."

### Daily reported Covid-19 cases in the U.S.

— Seven-day rolling average



Note: For all 50 states and D.C., U.S. territories and cruises. Last updated July 8, at 9:47 a.m.

Source: Johns Hopkins Center for Systems Science and Engineering

The trial is being funded with \$34.6 million from the Defense Department, which is looking for drugs that could help military units finding it difficult to do their work while maintaining social distance.



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The partners are still working out the details, including the number of subjects and the start date. They must also get permission from the Food and Drug Administration to conduct the study.

Investigators said they would draw from previous work using hyperimmune globulin products in the prevention of diseases such as hepatitis B to set up the study. The researchers said they hope to meet with the FDA soon to discuss the design of the trial.

Convalescent plasma, as the plasma taken from recovered patients is known, has emerged as a promising, though unproven, treatment for Covid-19.

Recently published results from an expanded-access study of the therapy involving 20,000 patients found that the transfusions resulted in few serious side effects and that there wasn't an excessive mortality rate. But investigators can't determine whether plasma improved outcomes because every patient in the study received it.



Donated convalescent plasma at a Delaware donor center in April.

PHOTO: NEW YORK BLOOD CENTER VIA ASSOCIATED PRESS

Researchers want to see whether drugs made by purifying antibodies taken from the donated blood could work better than the convalescent plasma. The drugs are known as Covid-19 hyperimmune globulin, or Covid-HIG.

The first of two trials sponsored by the National Institute of Allergy and Infectious Diseases testing Covid-HIG as a treatment will begin in seriously ill hospitalized patients later this summer.

The study by Emergent and Mount Sinai would explore whether such a drug could protect against infection.

Under the terms, ImmunoTek Bio Centers LLC, which manages and operates plasma-collection centers, would provide Mount Sinai with the machines to collect plasma from recovered Covid-19 patients at the hospital. ImmunoTek's FDA-approved license would be extended to Mount Sinai to set up plasma collection on site.

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Mount Sinai would ship the plasma to Emergent, of Gaithersberg, Md., which would manufacture the Covid-HIG drug to be studied in the trial.

There are many advantages to using a Covid hyperimmune product over convalescent plasma, said Mount Sinai's Dr. Aberg.

"It is a consistent amount of antibody in every lot number, rather than depending on whatever the antibodies of one particular donor is with convalescent plasma," Dr. Aberg said.

Yet researchers must explore what antibody level would provide protection to people and what the duration of that protection would be, she added.

The trial would test health-care workers and others at high risk of exposure to the new coronavirus. Half would be randomly assigned to receive the Covid-HIG product, and the other half would get saline.

Military personnel would receive the product under an expanded-access protocol, in which everyone enrolled receives the therapy, according to Laura Seward, senior vice president and therapeutics business unit head at Emergent.

Army Col. Ryan Eckmeier of the Defense Department said hyperimmune globulin, which has been used to prevent outbreaks of other diseases, could help military units that can't avoid close contact train and conduct missions.

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“Covid-19 outbreaks in the military cause a significant risk to readiness and the ability to conduct training and perform our mission,” he said in a statement.

Both Emergent and Mount Sinai are also participating in the National Institute of Allergy and Infectious Diseases trials that will study Covid-HIG's use as a treatment.

In April, the U.S. Department of Health and Human Services awarded Emergent \$14.5 million to develop Covid-HIG as a potential treatment to be tested in hospitalized patients and a second trial involving patients who are at high risk of progressing to severe disease.

The product Emergent makes from the plasma collected at Mount Sinai would be used both in the prophylaxis trials and the treatment trials, for which Mount Sinai is also one of the study sites. Emergent is one of several companies working with the NIAID on the treatment trials.

H. Clifford Lane, deputy director for clinical research and special projects at the NIAID and a senior member of the protocol team, said the plan is to enroll 500 subjects in the treatment study involving hospitalized patients.

He said a prevention study would require more patients.

## PLASMA RESEARCH

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[Study Points to Efficacy of Convalescent Plasma for Covid-19](#)

[U.S. Seeks Large-Scale Expansion of Blood-Plasma Collection for Covid-19](#)

[Blood Banks, Pharma Join Microsoft to Sign Up Covid-19 Survivors for Plasma](#)

[Convalescent Plasma Is Safe to Treat Covid-19, National Study Shows](#)

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