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OPINION | COMMENTARY

## The Treatment That Could Crush Covid

Early trials show signaling cells eliminate the virus, calm the immune response and repair tissue damage.

By Kevin Kimberlin Aug. 13, 2020 7:18 pm ET



**ILLUSTRATION: MARTIN KOZLOWSKI** 

More than 500 clinical trials are under way world-wide in the race to find an effective treatment for Covid-19. Everybody wants it; nobody has it—yet. But one of the most promising therapies for Covid-19 patients uses "medicinal signaling cells," or MSCs, which are found on blood vessels throughout the body.

In preliminary studies, these cells cut the death rate significantly, particularly in the sickest patients. With a powerful 1-2-3 punch, these cells eliminate the virus, calm the immune overreaction known as a cytokine storm, and repair damaged lung tissue—a combination offered by no other drug. This type of regenerative medicine could be as revolutionary as Jonas Salk's polio vaccine.

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In one pilot study in March, doctors at Mount Sinai Hospital in New York treated a dozen severely ill Covid-19 patients on ventilators with MSCs. Two infusions modulated their hyperactive immune systems, and 83% of those patients survived. With such promising results, the team at Mount Sinai and the supplier of the cells, Mesoblast Ltd., won Food and Drug Administration clearance and National Institutes of Health funding to conduct a randomized trial on

300 patients. The first patients in the trial received the treatment in early May.

A July 10 <u>article in the Lancet</u> reported on 13 critically ill Covid-19 patients also treated with MSCs. Eleven of the 13 patients lived—an 85% survival rate, which mirrors the results from Mount Sinai. The number of virus-fighting T-cells rose even as inflammation fell, suggesting that these cells can control the immune response as needed. In addition, chest X-rays showed that the drug repaired lung tissue, in some cases within 48 hours.

Healing tissue is essential because the cytokine battle with the Covid-19 virus is so vicious that it punches holes in the delicate lung membranes, allowing the virus to flood into the bloodstream and body cavities. These holes must be repaired, as virus leaks create some of the complications not usually associated with respiratory infections—blood clotting, heart attacks, stroke and multiple organ failure, which cause about 40% of Covid-19-related deaths. Blood-vessel density, and thereby the number of MSCs, decreases as we age, gain weight or develop diseases, which may explain why the elderly and those with chronic health conditions are faring worst.

In other words, this disease appears to be both a respiratory and a vascular infection. That is why the ability to fight infection, control the immune response and repair damaged tissue is such a valuable combination.

How can one drug do all this? MSCs were first identified and named by Prof.

Arnold Caplan and colleagues at Case Western Reserve University in Ohio nearly

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30 years ago. To translate this discovery into therapies, Mr. Caplan and I in 1993 launched Osiris Therapeutics, Inc. which developed this MSC into the world's first approved systemically delivered cell therapy. During early years of scientific inquiry, Mr. Caplan and colleagues discovered that MSCs monitor and protect virtually every vessel in our bodies—the 60,000 miles of vessels that transport oxygen, nutrition and waste to and from every one of our cells.

When a MSC detects an infection or an injury to those vessels, it transforms into a factory to recruit and pump out immune-modulating and vessel-repair agents. These cells ameliorate crippling and deadly conditions when traditional chemical or biochemical drugs fail. The number of potential uses is enormous. MSCs are being tested on more than 900 different human ailments. Mr. Caplan describes these cells not as a "wonder drug," but as a wonder drugstore.

Consider the results from trials conducted by Mesoblast on graft-versus-host Disease. Children with this horrible affliction suffer such a violent immune reaction that the skin and the lining of their intestines peel off. Up to 80% of children die if steroids don't stop the inflammation. But in one trial, 160 of 239 patients (67%) who didn't respond to steroids and other treatments survived after infusion with MSCs. Their cytokine storm disappeared. Injured tissues normalized. Based on these results, the FDA agreed to expedite its review and grant a decision by Sept. 30.

This is exactly the type of cell being tested for Covid-19 in the May trial. If the cells perform as they did at Mount Sinai in March and elsewhere, the results should be available before the end of September. A positive finding could help those most at risk of the disease's worst effects. But the medical community and wider public are largely unaware of the potential for using MSCs to treat Covid.

Amid so much darkness, MSCs are a ray of hope—not only for the most desperate coronavirus patients, but all of us ready to end the pandemic and discover new ways to fix the body's broken systems.

Mr. Kimberlin is chairman of Spencer Trask & Co. and a co-founder of Osiris Therapeutics, Myriad Genetics and Ciena Corp.

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