

Ebola drug ZMapp may help, but is not a miracle cure

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Transmission electron microscope image of negative-stained, Fortaleza-strain Zika virus (red), isolated from a microcephaly case in Brazil. The virus is associated with cellular membranes in the center. Credit: NIAID

ZMapp, once touted as a miraculous "secret serum" against the deadly Ebola virus, has shown some success but fell short of the bar for effectiveness in a clinical trial, researchers said Wednesday.

Still, experts pointed out that ZMapp helped more people survive, compared to those who received the standard therapy of intravenous fluids and medical care.

"It is likely that this drug had a significant effect. It is not a miraculous effect," said Jesse Goodman, a doctor and infectious disease expert at Georgetown University who was not involved in the study.

A total of 37 percent of patients died after receiving standard treatment alone, compared to 22 percent who died after receiving standard therapy plus ZMapp, made by Mapp Pharmaceuticals in San Diego, California, according to the study in the *New England Journal of Medicine*.

Those who were given ZMapp saw a 40 percent lower relative risk of dying than those who did not get it.

Statistically, this meant a 91 percent likelihood that ZMapp was better than the current standard of care alone.

Before the trial began, researchers established that the drug would have to meet a 97.5 percent probability threshold to be declared superior to hydration and hospital care.

A key setback for the phase II clinical trial undertaken in Sierra Leone, Guinea, Liberia and the United States was that the deadly epidemic was winding down by the time the research got under way.

Only 72 people enrolled instead of the hoped-for 200 patients during the study which ran from March 2015 to January 2016.

The Ebola outbreak swept across West Africa from late 2013 to until 2016, and killed more than 11,000 people.

Fears of contagion

Ebola is spread by contact with bodily fluids, and causes a range of symptoms, from fever and body aches to vomiting, diarrhea and hemorrhage.

According to the World Health Organization, Ebola has killed up to 90 percent of those infected during some outbreaks, though the average chance of survival is about 50-50.

There is no drug on the market to treat Ebola.

As an experimental therapy not yet approved by regulators, ZMapp was granted fast-track status by the US Food and Drug Administration last year, a designation aimed at speeding its arrival on the market.

At the height of the Ebola epidemic, ZMapp rose to fame as the possible reason why some patients had reached the brink of death and survived.

It was touted as key reason why American missionary Kent Brantly was able to pull through, after becoming infected while treating Ebola patients in Liberia.

Grown in tobacco leaves, ZMapp was also scarce, with a limited amount of doses ever made.

It even stoked controversy when some claimed that white missionaries were more likely to receive it than African patients and medical workers who fell ill.

But a top doctor in Sierra Leone, Martin Salia, who also became sick with Ebola while treating patients, was given ZMapp and died anyway. Doctors later said it appeared his disease had been too advanced by the time he was treated.

Trial's end

ZMapp announced preliminary results from the trial in February, but the full analysis was not published until Wednesday.

In a statement, Kevin Whaley, CEO of Mapp Biopharmaceutical, said the company would "vigorously pursue further development and licensure of ZMapp as a treatment for Ebola."

The trial also showed that overall, 30 percent of patients in the study died from Ebola within 28 days of seeking treatment, far lower than the sky-high mortality rates that circulated at the start of the outbreak.

Patients with higher viral load also appeared to succumb to Ebola more often.

"Seven of the eight deaths recorded in ZMapp recipients occurred before day 4 - that is, before the second of three planned infusions of ZMapp," said the study.

Martin Friede, the Coordinator of the Initiative for Vaccine Research for the World Health Organization, described the results as "encouraging," and said ZMapp appears most effective when patients are treated early.

Even though ZMapp did not meet its mark in the phase II randomized trial, Goodman said it is "the only one with data that really suggests efficacy, because it was the only one where there was a trial with a meaningful control group."

More information: , A Randomized, Controlled Trial of ZMapp for Ebola Virus Infection, *New England Journal of Medicine* (2016). DOI: 10.1056/NEJMoa1604330

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