Coronavirus treatment

Hepatitis C drugs help combat Covid-19 in trials

US official Anthony Fauci says sofosbuvir and daclatasvir results are 'provocative and encouraging'



The death rate for those given a combination of sofosbuvir and daclatasvir was just 5 per cent compared with 20 per cent for those who were not © Ali Khara/West Asia News/Reuters

Donato Paolo Mancini in London and **Najmeh Bozorgmehr** in Tehran 8 HOURS AGO

A combination of antiviral drugs used to cure millions of Hepatitis C patients has shown promising results as a Covid-19 treatment in hospital trials in Iran.

In results from three trials, 94 per cent of hospitalised patients taking a combination of sofosbuvir and daclatasvir showed reduced fevers and improved breathing versus 70 per cent in the control arm.

The death rate for those given the drugs was just 5 per cent compared with 20 per cent for those who were not.

Anthony Fauci, the head of the US National Institute of Allergy and Infectious Diseases and a member of the coronavirus task force, told reporters the results were "really quite interesting and provocative and encouraging".

"We desperately need antivirals that can be given early on in the course [of the disease] to prevent individuals from requiring hospitalisation," he said. "I'd encourage that we do further studies to nail this down."

The two antivirals join dexamethasone and remdesivir on a list of repurposed existing drugs that have been found to have a positive effect on coronavirus patients and are already being used in clinical settings.

Sofosbuvir and daclatasvir, which are widely available globally as generics, work by interfering directly with viral activity.

The studies used Sovodak, a combination of sofosbuvir and daclatasvir, in four university hospitals in three Iranian cities. Sovodak is made by Rojan Pharma, a private Iranian generics manufacturer.

Although US sanctions do not apply to food and medicine, Iranian authorities have warned that they are making the import of drugs complicated and expensive and occasionally cause shortages in the market.

Shahin Merat, a trial investigator and professor at the Tehran University of Medical Sciences, told the Financial Times: "Because of the sanctions, most drugs were not available to us early enough. We had no choice other than to work with what we have... This one, it turned out, appears to work." Dr Merat owns shares in Rojan Pharma.

The trial results were presented on Thursday at an international HIV/Aids conference.

Sofosbuvir was invented by Pharmasset, a company later acquired by Gilead, according to a World Health Organization <u>document</u>. It is patent-protected in the US but not in Iran and other countries. Daclatasvir used to be manufactured by Bristol-Myers-Squibb but the American company no longer makes it.

Prices for the combination, given for two weeks, range from over \$18,000 for certain patients in the US to about \$4,200 in Brazil to \$6 in Pakistan.

Andrew Hill, a researcher at the University of Liverpool and an investigator on the study, concluded in a paper published this year that the sofosbuvir-daclatasvir combination could be made at a small profit for approximately \$5 for a two-week treatment course.

Dr Thiago Souza, a study investigator at Rio de Janeiro's Laboratório de Imunofarmacologia, said laboratory studies have shown daclatasvir is effective against the virus on its own, penetrating the lungs where infection can be concentrated. Sofosbuvir, used in isolation, only has a marginal effect on coronavirus, he added.

<u>A separate study</u>, which included Gilead scientists, showed sofosbuvir, among other antivirals, had no effect on the new coronavirus at standard doses.

Dr Hill said: "There is already enough generic sofosbuvir and daclatasvir massproduced to treat millions of people if this drug proves effectiveness in large trials. We want this treatment to be affordable for anyone with Covid-19 infection, in any country."

Iran has stockpiled enough of the drugs to treat about 4,000 cases, the use it normally sees yearly for hepatitis C, Dr Merat said, but it is being depleted as demand for the drug surges. "We are already running low on Sovodak," he added.

The trials enrolled a small number of patients -176 — and one of them was not properly randomised, the researchers warned.

"Small, open-label trials could be prone to biases, so these results need to be seen as preliminary, unless confirmed with larger double-blinded placebo controlled trials," they said.

Before the trial results were announced, Kianush Jahanpur, an official at Iran's health ministry, told the FT sofosbuvir was not officially recommended as there was "no strong evidence" it would be effective. He said the drug "is currently prescribed only at a limited level for clinical trials and experimental studies".

Patients in the control arms received hydroxychloroquine alone or in combination with a HIV drug combination of lopinavir and ritonavir.

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Larger trials testing the drug combination are also under way in Brazil, Egypt and South Africa, involving more than 2,000 patients. Results are expected later this year.

Bristol-Myers Squibb said that if further trials confirm efficacy, it will continue to work to ensure availability of the drug. The company has provided the royalty-free licence for the drug to the Medicines Patent Pool, it said, which enables widescale generic manufacturing.

The only other antiviral currently to have some form of regulatory approval against Covid-19 is remdesivir, which is made by Gilead. The drug has shown a statistically significant effect on the length of hospital stays for patients, although it has not reduced mortality.

Last week, the US secured virtually all company-made supplies of the drug until the end of September. Critics and activists have said that the drug's price tag, \$2,340 a course, is too high. Gilead said it is justified because shorter hospital stays entail savings for healthcare providers.

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