

## Federal Study of Covid Treatments Enters a New Phase

### 聯邦研究新冠肺炎治療進入新階段

By Gina Kolata

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English	繁體中文
<p><i>A clinical trial showed that remdesivir helped hospitalized patients. Now researchers are asking whether when the drug is paired with another antiviral drug, patients will recover faster.</i></p>	<p>一項臨床試驗顯示，瑞德西韋(remdesivir)可以幫助住院患者。現在，研究人員正在查證這種藥物是否可以與另一種抗病毒藥物搭配使用，而令患者更快康復。</p>
<p>A large federal study that found an antiviral drug, remdesivir, can hasten the recovery in hospitalized Covid-19 patients, has begun a new phase of investigation.</p>	<p>一項大型聯邦研究發現，抗病毒藥物瑞德西韋可以令住院的新冠肺炎患者加速康復，該研究已進入新階段。</p>
<p>Now it will examine whether adding another drug, beta interferon — which mainly kills viruses but can also tame inflammation — would improve remdesivir’s effects and speed recovery even more.</p>	<p>現在，會研究是否添加另一種藥物--β干擾素；這主要殺死病毒，但也可以抑制炎症--會改善瑞德西韋的效用，並加快康復。</p>
<p>So far, remdesivir, an experimental drug, has received emergency use approval from the Food and Drug Administration to treat hospitalized Covid patients. In a large clinical trial, sponsored by the National Institutes of Health, remdesivir was shown to modestly shorten recovery time, by four days, on average, but it did not reduce deaths.</p>	<p>到目前為止，試驗藥物--瑞德西韋已經獲得了美國食品和藥物管理局的緊急使用許可，以治療住院的新冠肺炎患者。在一項由美國國立衛生研究院贊助的大型臨床試驗中，瑞德西韋可將康復時間平均縮短4天，不過，它並未減低死亡人數。</p>
<p>The additional drug, beta interferon, has</p>	<p>新增的一種藥物--β干擾素已經被批准用於治療多發性硬化症，以利用其抗炎作用。</p>

already been approved for treatment of multiple sclerosis, which takes advantage of its anti-inflammatory effect.

The U.S. trial, known as **ACCT**, is designed to move quickly. Known as an adaptive trial, it is a race between treatments. It tests one treatment against another and when results are in, the drug that won that phase becomes the control drug for the next phase, in which it is tested against a different drug.

The new phase is the study's third. A total of 1,000 patients will receive either remdesivir and a placebo or remdesivir and beta interferon.

Interferon is given as an injection. Remdesivir, made by Gilead Sciences, is given as an intravenous infusion.

A team of researchers held multiple group conference calls trying to select the new test drug for Phase 3, Dr. Peter Chin-Hong, an infectious disease expert at the University of California in San Francisco, said.

Their first suggestion was to try adding an experimental drug made by Merck known as EIDD-2801, which, like remdesivir, is an antiviral but is a pill. But they wanted something that had already been approved and available for other diseases. They hoped that by showing that the new drug was effective, and had already been approved for other illnesses, that doctors

一項稱為“**新冠肺炎適應治療試驗**”正在美國迅速展開。作為一種適應性試驗，它在各種療法之間在進行競賽。試驗是以一種療法跟另一種療法作比對，當獲得結果時，贏得該階段的藥物會成為下一階段的基準藥物，並以此再跟另一種藥物進行比拚。

新階段已是研究的第三階段。總共有 1,000 名患者將接受瑞德西韋加上安慰劑或瑞德西韋加上β干擾素治療。

干擾素為注射劑，而由吉利德科學公司 ( Gilead Sciences ) 生產的瑞德西韋則為靜脈輸注液。

加州大學舊金山分校的傳染病專家陳子平醫學博士說，一組研究人員舉行了多次小組電話會議，為第三期尋求新的試驗藥物。

他們首項建議是嘗試添加一種由默克公司 ( Merck ) 生產，稱為 EIDD-2801 的實驗藥物；該藥物與瑞德西韋一樣，是抗病毒藥，不過，它是藥片。但是，他們想要的是一種已經被核准並且可以用於其他疾病的物品。他們希望證明新藥有效，並且已經被批准用於其他疾病，醫生便可以馬上將其應用在新冠肺炎患者。

該小組也有考慮地塞米松

could immediately give it to Covid patients.

The group also considered dexamethasone, a common steroid that seems to be effective in reducing the death rate in severely ill patients. The drug, which suppresses inflammation, might be even better when added to remdesivir, the researchers reasoned.

But they worried. Dexamethasone is inexpensive and easily available. With widespread publicity over its apparent effectiveness, many patients would balk at joining a study in which they might get a placebo.

Then the group weighed using beta interferon, which had several things going for it. It is on the market as a treatment for multiple sclerosis, because of its weak anti-inflammatory properties. It kills the new coronavirus in laboratory studies and it kills SARS and MERS, which also are coronaviruses.

And, most impressive, Dr. Chin-Hong said, the drug was tested twice in Covid patients, with promising results. One test was in England, where beta interferon or a placebo was provided to 101 hospitalized patients. They inhaled it in a nebulizer, a device like the ones used to deliver asthma medications.

The study, although small, found that those who had received the drug recovered better than those who had received a

(dexamethasone) ，一種常用的類固醇，似乎可以有效降低重症患者的死亡率。研究人員認為，把這種抑制炎症的藥物加進瑞德西韋後可能會更好。

不過，他們卻擔心 - 地塞米松並不昂貴，也容易得到。由於其明顯的功效而受到廣泛宣傳，許多患者也許不願參加一項可能只得到安慰劑的研究。

然後，該小組評估β干擾素，並發現它有幾種優點。由於其弱抗炎特性，它在市場上成為多發性硬化症的治療劑。它在實驗室研究中殺死了新的冠狀病毒，並殺死了嚴重急性呼吸道綜合症病毒(SARS)和中東呼吸綜合症病毒(MERS)，它們都屬於冠狀病毒類。

陳子平醫學博士說，最令人印象深刻的是該藥物在新冠肺炎患者中進行了兩次試驗，結果都令人滿意。一次在英國，給 101 名住院患者提供了β干擾素或安慰劑。他們將其吸入霧化器中，該霧化器類似用於輸送哮喘藥物的裝置。

這項研究規模雖然細小，但發現接受藥物治療的患者比接受安慰劑的患者康復較佳。

另一項研究則在香港進行，涉及 127 位接

placebo.

The other study, in Hong Kong, involved 127 patients who received beta interferon along with two antiviral drugs. The patients were hospitalized but many were not severely ill. The drug cocktail was superior to placebo in speeding recovery.

But the U.S. trial will be the only large rigorous trial to test beta interferon in Covid patients.

The first phase involving remdesivir began on Feb. 21, testing the experimental drug against a placebo. That phase closed on April 19 after 1,000 patients had been enrolled. The National Institute of Allergy and Infectious Diseases, which is sponsoring the study, announced preliminary results on April 27.

The next phase began on May 8, testing remdesivir and a placebo against remdesivir and baricitinib, an arthritis drug that quells inflammation. Researchers hoped that the addition of the arthritis drug would improve patients' outcomes by stemming an overreaction of the immune system to the virus, a so-called cytokine storm, which can occur in severely ill patients and can be lethal. After 1,000 patients were enrolled and followed, that part of the study was closed.

Results of Phase 2 are still being evaluated. Dr. Chin-Hong said that he and others were fairly certain that if adding the arthritis

受β干擾加上兩種抗病毒藥物治療的患者。病人已經住院，但許多的病情並非嚴重。該混合藥物在加速康復方面比安慰劑優勝。

不過，在美國進行的新冠肺炎患者β干擾素試驗將會是唯一大型且嚴格的一次。

涉及瑞德西韋的第一階段於 2 月 21 日開始，試驗乃以實驗藥物與安慰劑作對比。在招募了 1,000 名患者後，該階段於 4 月 19 日結束。贊助這項研究的美國過敏和傳染疾病研究所於 4 月 27 日宣布了初步結果。

下一階段於 5 月 8 日開始，是以瑞德西韋加上安慰劑跟瑞德西韋加上 Baricitinib（一種抑制炎症的關節炎藥物）作對比的試驗。研究人員希望，將關節炎藥物加入試驗或會阻止免疫系統對病毒的過度反應，從而改善患者的預後。而這種被稱為“細胞因子風暴”的病毒可能會出現在重症患者身上，並具有致命性。在招募並追蹤了 1,000 名患者之後，該部分研究已經結束了。

第二階段的結果仍在評估中。陳子平醫學博士說他和其他人員相當確定，**如果發現添加關節炎藥物 baricitinib 之後根本沒有幫助，就不會產生很大作用。**如果該藥物顯示出顯著的效果，則負責監督該試驗的研究數據安全和監視委員會將終止該試驗，並為每位患者提供瑞德西韋和

drug, baricitinib, were found to have helped at all, the effect would not have been huge. If the drug had demonstrated an impressive effect, the study's data safety and monitoring board, which oversees the trial, would have halted it and given every patient remdesivir and baricitinib. That combination would then have been the control drugs for Phase 3 of the study.

That did not happen.

Rather than wait while the data with baricitinib could be fully evaluated, the study has moved on to its next phase, testing remdesivir and placebo against remdesivir and beta interferon.

Enrollment began this month.

At the University of California in San Francisco and San Francisco General, nine patients have joined so far.

"We are approaching another today," Dr. Chin-Hong said on Monday.

baricitinib。那麼，這組合將會成為該研究第三階段的基準比對藥物。

那並沒有發生。

與其等到完成評估 baricitinib 的數據，這項研究已經進入了另一階段，即是針對瑞德西韋加上安慰劑與瑞德西韋加上  $\beta$  干擾的比對試驗。

本月開始報名。

到目前為止，在舊金山的加州大學和舊金山綜合醫院，已有 9 名患者參加。

陳子平醫學博士星期一說，“今天我們會聯絡另一名。”