

# THE COVID-19 PANDEMIC AND HAEMOGLOBIN DISORDERS

**VACCINATIONS &  
THERAPEUTIC  
DRUGS**

**WEEKLY UPDATES**



**THALASSAEMIA  
INTERNATIONAL  
FEDERATION**

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## **Vaccinations and Therapeutic Drugs**

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1. **BioNTech and Pfizer** vaccine: Phase I/II dose escalation study on 360 healthy volunteers in the US has currently started in early May.
2. **Moderna**: In early May, the company received permission from the FDA to start a phase II study of its vaccine. The company expects to start a phase III clinical trial in early summer.

## **Therapeutic Drugs**

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1. Stanford University has initiated a clinical trial of **peginterferon lambda-1a**. This treatment increases the immune system and has been used to treat viral hepatitis. the university has moved to a phase 2, open-label, single-blinded, randomized trial of a single dose of Peginterferon Lambda-1a compared with placebo in outpatients with mild COVID-19. Study participants will be randomly assigned 1:1 to a single subcutaneous dose of Peginterferon Lambda-1a or placebo along with the standard of care. The primary outcome will be duration of viral shedding in respiratory secretions by of SARS-CoV-2 qRT-PCR in 28 days of follow up. About 120 volunteers in early stages of the infection (within 3 days of being found positive to the virus) will followed for disease progression.

In addition, the University of Southampton and a UK bio-tech company Synairgen, are also initiating a clinical trial involving interferon.

2. The National Institute of Allergy and Infectious Diseases study of Remdesivir, met an evolving primary endpoint, namely **Remdesivir** helped COVID-19 patients recover faster. These positive initial results, announced on April 29, led the Food and Drug Administration subsequently to authorize the emergency use of Remdesivir for patients hospitalized with severe cases of COVID-19.

In addition, a randomized, controlled clinical trial evaluating the safety and efficacy of a treatment regimen of the **antiviral remdesivir plus the anti-inflammatory**

**drug baricitinib** for coronavirus disease 2019 (COVID-19) has begun. The trial is now enrolling hospitalized adults with COVID-19 in the United States. The trial is expected to open at approximately 100 U.S. and international sites. Investigators currently anticipate enrolling more than 1,000 participants. This trial is under the National Institute of Allergy and Infectious Diseases (NIAID) [Baricitinib is a product licensed to Eli Lilly and Company by Incyte and marketed under the brand name Olumiant, is approved in the U.S. and in more than 65 additional countries as a treatment for adults with moderately to severely active rheumatoid arthritis].

3. **Kaletra, a combination of lopinavir and ritonavir**, (anti- HIV combination), in one small study (published May 4 in the journal Med, Cell Press) involving 86 patients, found that Kaletra did not improve outcomes in people with mild or moderate COVID-19 compared to those receiving standard care. These findings were confirmed in another trial (published May 7 in the New England Journal of Medicine).
4. However, if **Kaletra** is given **along with ribavirin and interferon beta-1b** — took less time to clear the virus from their body (published May 8 in The Lancet). Larger phase 3 trials are needed to examine the effectiveness of this triple combination in critically ill patients.
5. **Hydroxychloroquine**: in two recent studies (in early May one in the New England Journal of Medicine and the other in JAMA reported that patients who had been given hydroxychloroquine didn't benefit. The medication didn't lessen patients' need for ventilators or reduce their risk of death. In the JAMA publication it was also found that hydroxychloroquine, with azithromycin, also did not help people with COVID-19.
6. **Favipiravir** (Avigan): In a recent trial in Russia, of 40 coronavirus patients who took a favipiravir pill, 60% tested negative for Covid-19 within five days compared to 30% in the control group. China has already completed clinical trials on favipiravir and also found the drug shortened recovery time for patients.
7. **Stem cell treatments**:
  - i. Athersys Inc. began a phase II/III clinical trial that will examine whether the company's stem cell treatment could potentially benefit people with acute respiratory distress syndrome (ARDS). This condition occurs in some people with severe COVID-19.

- ii. Another company, Mesoblast, has also developed a potential stem cell treatment for ARDS. The company is enrolling people with moderate to severe ARDS into a phase II/III clinical trial in the United States.