ANTICOV: Clinical trial for COVID-19 in low-resource settings to test a new combination treatment

February 10 2022

Satellite imagery of Africa. Credit: Public Domain

The ANTICOV platform clinical trial has started the recruitment of

participants to test a new promising drug combination, fluoxetine and budesonide, as an early treatment for people affected with mild-to-moderate COVID-19.

The ANTICOV trial, currently conducted in 13 African countries and soon expanding to additional countries in South Asia and Latin America, aims to identify COVID-19 treatments that are optimized for use in resource-limited settings and can prevent progression to severe disease and potentially limit transmission.

"We urgently need to identify an oral COVID-19 treatment that is safe, affordable, accessible and adapted to the specific needs of low- and middle-income countries (LMICs)' said Nathalie Strub-Wourgaft, Director of the COVID-19 Response for the non-profit research and development (R&D) organization the Drugs for Neglected Diseases initiative (DNDi), which coordinates the ANTICOV consortium.

"COVID-19 antivirals recently approved for use in the United States, the European Union, India, and other countries show some promise on preventing disease progression when administered to high-risk patients in the first five days of symptoms. Concerns are growing whether these antivirals will be immediately available to everyone who needs them, especially in regions where access to vaccines remains unacceptably low. In low-income countries, less than 6% of people have been fully vaccinated against COVID-19," Dr. Strub-Wourgaft said.

The new drug combination tested by ANTICOV includes fluoxetine, better known under its brand name Prozac. Fluoxetine's potential for COVID is based on a mechanism of action that is totally separated from its anti-depressant properties: it inhibits the ability of the virus to replicate by preventing viral entry into cells and could also carry immunosuppressive activity. It is safe and widely available. Another molecule belonging to the same class of compounds was shown in

August by the TOGETHER study to be effective against COVID-19, reducing deaths and hospitalizations by up to 30%.

Fluoxetine will be tested in combination with inhaled budesonide, a safe and affordable inhaled corticosteroid known to have potent anti-inflammatory efficacy in the lungs. Studies have shown that budesonide, if taken in an early stage of the infection, improves recovery time in outpatients with COVID and may reduce hospitalizations and deaths.

"For outpatients presenting for treatment within a week of symptom onset, which corresponds to the reality on the ground, oral drugs combinations that are adding two different mechanisms of action—an antiviral and an anti-inflammatory—are the most promising options," said Dr. Strub-Wourgaft. "Such a treatment will be particularly adapted to limited-resource settings where affordable testing tools are often difficult to access."

The combination could be effective for the first, viral replication stage of the infection and could also decrease the likelihood of the second, inflammatory stage that can start a few days later.

Fluoxetine and budesonide are commercially available and will be affordable and easy to access and administer, if shown to be effective against COVID-19. This is the fifth arm tested by the ANTICOV trial since its launch in November 2020.

ANTICOV is an 'adaptive platform' trial, a flexible and innovative trial design that allows for treatments to be added or removed as new evidence emerges. The selection of drugs for ANTICOV is informed by reviews conducted by the expert working group of the Unitaid and Wellcome-led Access to COVID-19 Tools Accelerator (ACT-A) Therapeutics Partnership.

Provided by Drugs for Neglected Diseases Initiative