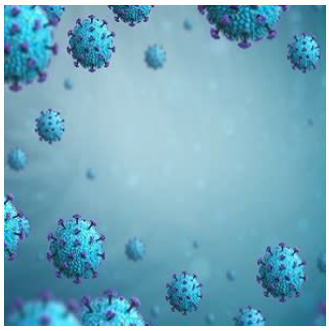
ICU
MANAGEMENT & PRACTICE

BLAZE Trial: Efficacy and Safety of LY-CoV555



COVID-19 patients can have a wide range of disease severity, with some patients experiencing only mild symptoms while others are infected quite severely. However, approximately 10% of asymptomatic and mild cases lead to severe outcomes, including respiratory distress that would require hospitalisation. Many risk factors for severe disease have been proposed, including old age, obesity, hypertension and underlying medical conditions, but the connection between viral load and outcomes has so far not been tested. Several treatment options have also been explored, including antimalarial drugs, antiviral drugs, immunomodulators, convalescent plasma, glucocorticoids etc. but again, the results have been variable. There is no large randomised, controlled trial of treatments specifically for SARS-CoV-2.

Results from preclinical studies of neutralising antibody treatments in animal models show promising results, demonstrating reductions in viral loads in both the upper and lower respiratory tracts. The SARS-CoV-2 virus gains entry into the cells by binding its spike protein to receptors for angiotensin-converting enzyme 2. LY-CoV555 is a potent antispike neutralising monoclonal antibody that binds to the receptor-binding domain of SARS-CoV-2. The Blocking Viral Attachment and Cell Entry with SARS-CoV-2 Neutralizing Antibodies (BLAZE-1) trial is an ongoing phase 2 trial designed to evaluate the efficacy and safety of LY-CoV555 in patients with mild or moderate COVID-19 in the outpatient setting. The researchers evaluated the effect of the antibody on viral load, symptom scores and clinical outcomes. The trial is being conducted at 41 centres in the U.S. Patients received a single intravenous infusion of LY-CoV555 or placebo monotherapy over one hour. The primary outcome was the change from baseline in the viral load at day 11 (±4 days) after testing positive.

Interim results from the trial show that by day 11, majority of the patients in the antibody group and the placebo group had a trend towards viral clearance. Researchers observed an association between slower viral clearance and more hospitalisation. On day 7, the viral load among hospitalised patients was higher compared to nonhospitalised patients. The frequency of hospitalisation in patients with higher viral load on day 7 was 12% compared to 0.9% in patients with a lower viral load. 1.6% of patients were hospitalised in the LY-CoV555 group on day 29, compared to 6.3% of patients in the placebo group.

As far as symptoms are concerned, the change in symptom score from day 2 to day 6 from baseline was better in the LY-CoV555 group compared to patients in the placebo group, and this trend continued from day 7 to day 11. No serious adverse events occurred in the LY-CoV555 group, and the rate of adverse events in the placebo group was 0.7%.

Overall, interim analysis of these findings shows that the viral load on day 11 was lower in the LY-CoV555 group compared to the placebo group. However, this decreased viral load did not appear to be clinically meaningful. Nevertheless, LY-CoV555 therapy shows a possible treatment effect. Hospitalisation rates were lower in the LY-CoV555 group suggesting a possible reduction in symptom severity and a link between a lower viral load and a lower frequency of hospitalisation. If these findings continue to show the same trend and are confirmed in additional analysis, LY-CoV555 could be a useful treatment for emergency use in patients with mild to moderate recently diagnosed COVID-19.

Source: NEJM

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