

## HCG to begin clinical trial of plasma therapy

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The specialist in cancer care receives permission from Government of India



As the number of COVID cases soar in India, HCG – the specialist in cancer finds a ray of hope to alleviate the patients diagnosed with the disease. In a positive development to the situation and adding hope to find a possibility to fight the virus, Bengaluru based HCG cancer hospital has received grant from Directorate General of Healthcare Services(DGHS), Government of India under the provisions of New Drugs and Clinical Trial Rules, 2019 to begin clinical trial of proposed Convalescent Plasma Therapy.

Convalescent Plasma Therapy is an experimental procedure for COVID-19 patients. In this treatment, plasma from a COVID-19 patient who has recovered from the disease is transfused into a coronavirus patient who is in critical condition. Passive antibody therapy, through transfusion of convalescent plasma, may prevent clinical infection or blunt clinical severity in individuals with recent pathogen exposure. Antibody therapy can also be used to treat patients who are already manifesting symptoms of varying severity.

Speaking about this *Dr. Vishal Rao, Associate Dean – Centre of Academics and Research, HealthCare Global (HCG) Cancer Centre* says, "The idea behind this therapy is that immunity can be transferred from a healthy person to a sick patient using convalescent plasma. This therapy uses antibodies from the blood of a recovered coronavirus patient to treat another critical patient. The recovered COVID-19 patient's blood develops antibodies to battle against COVID-19. Once the blood of the first patient is infused to the second patient, those antibodies will start fighting against coronavirus in the second person." He also added, "HCG has always believed in multi-disciplinary team approach, therefore to ensure that clinical trial is successful, we have on board Immuno-Haematologist, Infectious diseases experts, Immunologist, Intensivist, Pulmonologist / Physician, Cell & molecular biologist diagnostics lab experts and Clinical Research Organisation (CRO) throughout."

Talking about the pipeline of clinical trials, Dr. Vishal added, "We have submitted 3 protocols from Karnataka to DCGI and ICMR for expedited review. These are - Cell-derived Cytokine Therapy Trial for Early stage COVID patients, Mesenchymal Cell therapy clinical trial - Moderate Stage and Convalescent plasma therapy Clinical Trial - Severe stage."

The research began during the initial days of the COVID scare, when *Dr. Gururaj A. Rao, Director, iCrest, HCG Cancer Hospital* decided to find out a possibility of treating COVID patients through Plasma Therapy along with colleagues and team.

He says, "The concept of convalescent plasma therapy has been used earlier in other situations such as EBOLA pandemic with some success so it made sense for us to think about exploring the utility of Plasma therapy in COVID patients. Recovered patients would have developed antibodies against the virus and we believe that these antibodies will help an ailing patient fight the virus and help in the recovery.

Dr. Gururaj further added, "We submitted our protocol to the drug controller after we obtained clearance from HCG ethics committee. After several reviews by the Drug controller special review committee and the ICMR committee, we have been granted permission to start the clinical trial. The efforts put by my colleagues Dr. Jyothsna, Research Director, iCREST, HCG and Dr. Ashish Dhoot, HOD, Transfusion Medicine, HCG is outstanding. As a team, we believe that convalescent therapy holds promise in severe cases of COVID.."

Supporting the clinical team's effort to create a solution, Dr. BS Ajaikumar, Chairman & CEO said, "This is a considerable development in the given crisis situation, and I appreciate the immunology team at HCG who have been working tirelessly to create evidence based solution for clinical trial. We thank the Government of India and Government of Karnataka for supporting the trial of the protocol. The trial will begin earliest in hospitals as identified by the Government following the mandate with the expertise of the HCG clinical team. HCG aims in creating solutions and offers value based medicine - basis cutting edge research. This time we will take a final decision on the effectiveness of the Plasma Therapy after the clinical trials are completed."

Dr. Ashish Dhoot, Consultant and Head, Blood Bank and Stem Cells, HCG said, "Convalescent Plasma Therapy is a form of Immuno-Therapy wherein we provide passive immunity through focused immunoglobulins to patients with severe COVID-19 infection, who were unable to launch an active, appropriate immunological attack on the virus. This therapy, if works good in our clinical trial, will help us save such sick patients requiring ICU support to get cured quickly and will reduce mortality and morbidity of this epidemic. Corona virus is a new/novel virus that has not just crossed the animal-human barrier but has also been successful in spreading from man to man. It has a very high infectivity and an unexplained high mortality. Adding to that, researchers have reported that some of the patients, after becoming virus negative, become positive again at a later stage. And surprisingly they remain healthy afterwards. The pathophysiology of the virus is a mystery that many scientists are working on currently."

This virus shares some of its antigenic characteristics with the HIV virus. This has helped us in treating the Corona virus patients with some of the antiviral drugs used for HIV infection. Some more and efficient drugs against it are on research, including Convalescent Plasma Therapy.