

COVID19 VACCINE TRIAL UPDATE AND THE SOLIDARITY STUDY

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Scientists, researchers and pharmaceutical companies have joined the race to develop vaccine against SARS-CoV-2 virus which causes covid-19 disease. Ordinary people are also high on expectations with claims making round on social media as if COVID-19 cure is just here. While the effort is on to find some solution at the earliest, this is what it looks like.

As confirmed by World Health Organisation , two candidate vaccines for covid-19 have entered 1st phase of clinical trials. Draft Landscape of Covid-19 reported that among these vaccines developed by CanSino Biological Inc & Beijing Institute of Technology uses non replicating viral vector as the platform. This Phase 1 trial began in March 16 , 2020 & expected to complete by December 31,2020.

Second to enter phase 1 trial is from US based biotech firm Moderna & the National Institute of Allergy & Infectious Disease (NIAID). It is Lipid Nanoparticle (LNP) encapsulated mRNA-based vaccine. Studies began on March 3,2020 .It is expected to give result by June 2021 as to what may be the future of Covid19 management.

There are 60 more vaccine candidates who are working on different mechanisms in Pre Clinical Trial Stage .The vaccine candidate from pre-clinical studies to three phases of clinical trials take **18-20 months** before coming out in market

SPEEDING UP- HUMAN CHALLENGE TRIAL

Challenging times call for extraordinary measures.

Scientists have come up with human challenge trial. A recent study published in the *Journal of Infectious Diseases*, the official (peer reviewed) journal of Infectious Disease Society of America mentioned the proposed model for human challenge trials for covid-19. Here healthy individuals will be chosen and will be given vaccine and small doses of virus. And they will be monitored to see the immune response against the virus. This will super speed up the vaccine trials without any doubt, but there are many ethical issues with this approach of infecting the healthy volunteers.

LAUNCH OF GLOBAL TRIAL OF 4 MOST PROMISING TREATMENT BY WHO

On March 18, 2020, the Director General of WHO announced the launch of SOLIDARITY trial to help find effective treatment. It is single Randomised trial which aims at enrolling patients in 1 trial to facilitate rapid worldwide comparison of unproven treatments so that time taken can be reduced by 80%.

This will overcome risk of small trials not generating strong evidence needed to determine relative effectiveness of potential treatment. It has simple procedure to allow even overloaded hospital to participate with less paperwork. As on April, 8 more than 90 countries joined the project. More countries faster results it would be.

Four Treatment options being considered in this trial are

Remdesivir drug used in Ebola treatment, Lopinavir/ Ritonavir used in HIV, MERS, SARS Lopinavir/ Ritonavir with interferon beta 1a (efficacious in Multiple Sclerosis) and Chloroquine /Hydroxychloroquine- Malaria and Rheumatological conditions.

Enrolling subjects may be easy. When person with confirmed covid-19 is deemed eligible, the physician can enter the patient's data with any other underlying condition that can change the course of disease and patients consent are entered into WHO website. After a physician tells which drugs are available in hospital, the system will randomize the patient to one of the treatment. The physician will then have to record directly on the day

patient leaves the hospital or died .

"It will be important to get answers quickly, to try to find out what works and what doesn't work. We think that randomized trial is the best way"- Ana Maria Henao Restrepo, World Health Organization.

The approach forward will be behaviour change along with early testing and identifying drugs or a vaccine that will lead the way. Behavioural change measures and early testing will reduce the number of infection.

As a short term approach, we are very hopeful with this trial and in coming weeks we will have evidence on best among these 4 treatment approaches to tackle this pandemic. Vaccines will play a role to avoid the situation to mitigate a Pandemic relapse.

About the Author:

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