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Emergency Protocol to use Mw vaccine as booster of Innate Immunity of doctors and HCWs looking after COVID 19⁺ Patients in Himachal Pradesh

Dr. Omesh Kumar Bharti

State Epidemiologist, State Institute of Health & Family Welfare, Shimla, Himachal Pradesh, India-171009
email; bhartiomes@yaho.com

Background: COVID pandemic has claimed 9, 22,252 lives globally with more than 28,928,900 positive cases till Sep 14, 2020¹. As we in Himachal Pradesh pass through a phase of community spread² and more and more doctors and Health Care Workers (HCWs) are getting infected, the need to have some emergency protocol to enhance innate immunity is being felt all over especially in a situation when no early vaccine is in sight. Innate immunity³ plays a vital role in fighting nonspecific pathogens especially viruses⁴ and boosting innate immunity of those caring for the COVID 19⁺ patients has now become an emergency.

We looked for all options of boosting innate immunity and finally thought of most safe, ready to use, DCGI approved immune-modulator Mycobacterium W (Mw) (Heat Killed)vaccine as the best choice in this hour, for emergency use, named Sepsivac⁵, that has a protective role in sever sepsis in ICU patients. While working in leprosy clinic at DDU Hospital, Shimla, we have seen the impact of Mw in those patients who were not responding to treatment of leprosy and that lead us to study about this vaccine leading to this emergency protocol.

BCG vaccination may provide specific protection against SARS-CoV-2⁶ and since BCG vaccine has also been proved to have nonspecific effects in modulating innate immune response and induce fast viral clearances in yellow fever about one month after inoculation⁷, Mw having antigenic similarity to BCG is supposed to have similar response. Other studies report COVID-19-attributable mortality among BCG-using countries was 5.8 times lower [95% CI 1.8-19.0] than in non BCG-using countries⁸ and protective role of Environmental Mycobacteria⁹. Sehgal et al have in a recent study, highlighted the safety of Mw vaccine in Patients with COVID requiring intensive care unit (ICU) admission¹⁰.

Protocol: We propose to administer 0.1 ml dose of Mw vaccine on skin of both deltoid muscle near deltoid insertion on day 0 followed by 0.1 ml booster of Mw vaccine after every three months up to a year or till vaccine for COVID 19 is available (Maximum 8 doses as booster), as innate immunity has a minimum duration of three months¹¹. The vaccine shall be sourced from the open market and if not available then from the company as CSR. Since general population in Himachal Pradesh is deficient of Vit D^{12, 13} it is mandatory that those to be vaccinated should have adequate levels of Vit D or supplementation shall be required with 60,000 IU per week for four weeks and then 2000 IU/day as this plays a very vital role in innate immunity¹⁴. Other vitamins like B-Complex and C should also be supplemented adequately apart from minerals like Zinc etc. The vitamins and minerals are essential components to generate adequate immune response by the body. Vaccinee shall continue to take other preventive measures like regular Hand washing, Social Distancing and use of Mask etc.

Mw vaccine is freely available in the market and we don't intend any maleficence in using Mw even if no benefit is accrued to Vaccinee in the longer run, since in emergency, we look for alternatives till a vaccine or drug is available to safeguard our health care force from getting infected from COVID 19. Moreover therapeutic potential of Mw vaccine is known in patients of COVID 19 admitted in ICU, therefore we can expect less severity of COVID 19 in people having Mw vaccination than those not having it.

OUTCOME Measurements:

1. Proportion of Vaccinee remaining asymptomatic of COVID, say over a period of one year (NO COVID19).
2. Proportion of Vaccinee remaining asymptomatic but having COVID antibodies after a period of one year.
3. Proportion of Vaccinee getting COVID Positive but asymptomatic, say over a period of one year.
4. Proportion of Vaccinee getting COVID Positive but had mild, moderate or severe COVID 19 disease as per Indian parameters, say over a period of one year along with outcome.

Consent Form

(To be filled by the potential Vaccinee)

Emergency Protocol to use Mw vaccine as booster of Innate Immunity of doctors and HCWs looking after COVID 19⁺ Patients in Himachal Pradesh

Dear Participant,

Since our doctors and HCWs looking after COVID 19⁺ Patients in Himachal Pradesh are at higher risk of infection and there is no COVID vaccine in sight and also no specific drug for COVID treatment is available, after careful research, we have thought of protecting them by administering Mw vaccine that is safe immunomodulator to boost innate immunity and have proven safety record even in patients who are critically ill. Before vaccination, we request you to fill the following consent form.

To be filled by Participant;

I, -----age-----sex-----am well aware of unprecedented circumstances of COVID 19 Pandemic and am aware that in discharge of my duties to COVID⁺ Patients, there is high likelihood of me getting infected with COVID. I have been explicitly informed that the vaccine is safe for use in humans, being a heat killed bacillus but may have rare side effects like injection site erythema and ulceration that may culminate into a shallow, self-healing ulcer by 3rd week which heals with scab formation by 4th week leaving a healed scar, rarely large ulcers, abscesses or Keloid formation may take place. I have also been instructed not to touch, rub, peel or apply anything at the site of the injection. In case of any adverse reaction, I shall inform the PI, Dr. Omesh Bharti (9418120302) and seek medical care from my hospital as advised. I know that Mw is a known immunomodulator approved by DCGI and is available in market for human use and is not a new drug or vaccine.

I understand that all my personnel information will be kept secret and will not be shared with anyone. My name will not be used in any report of this study. I know that if I still don't wish to be a part of this Mw study, I can opt out at any time, at any stage, without assigning any reason thereof.

Declaration by Participant: "I have read the contents of this consent form or the contents of this form have been read out to me in simple language I fully understand. I have had the opportunity to ask questions about this study and any questions I have asked have been answered to my satisfaction. I consent voluntarily to take part in this methodology and understand that I have the right to withdraw from this at any time without giving any reason."

Sign of the Participant with Address and Mobile number:-

Sign of the witness with address and mobile number:-

Date/ Place

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