It has been noticed that the Ministry of Health and Family Welfare, Government of India publishing advertisement seeking application for the “National Florence Nightingale Nurses Award” to recognize meritorious services of Nurses working in the State, Central, Autonomous Institutions, Private, Missionary and Voluntary organization in India. This award is being given on 12th May every year to recognize the service of a Nurse in India, which will in turn encourage other Nurses. Similar award is given to recognize doctors on 1st July every year, which will encourage doctors to serve better the society. Though two important health providers are being recognized, very unfortunately the third important health providers –“Pharmacists” are ignored till date. A few years back Her Excellency Mrs. Prativa Patil, the then President of India, in a programme at New Delhi declared that similar award will be given to the Pharmacist to recognize their contribution to the health care system. Very unfortunately that has not happened till date. It may be due to bureaucratic delay or may be lack of persuasion by the pharmaceutical Organizations and Pharmacy Council of India. It is high time that all pharmaceutical organizations be united and pursues the matter. The Pharmacy Council of India has extra responsibility in this matter being the highest authority of pharmacists. Hope we will see a similar advertisement seeking recommendation for such an award along with the next advertisement seeking recommendation for “Florence Nightingale Award” and “Dr. B.C. Roy Award”.

It is further noted that all stake holders in fighting against COVID are recognized by the Central Govt. and the state Govt. on Independence Day, but there is no report about recognizing Pharmacists as COVID warrior. This attitude of governments should be changed for encouraging pharmacists who are working at the frontline to fight against COVID pandemic and some of them have lost their lives. The question of entire profession of Pharmacy how much sacrifice to be done to get attention of the Governments?

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Show cause notice to Serum Institute of India by DCGI

BIO/CT/20/000095
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization (Biological Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Dated: 09.09.2020

Subject: - safety concerns of ChAdOx1 nCoV-19 Corona virus vaccine (recombinant) during ongoing clinical trial - show cause notice issued — regarding.

Whereas, the undersigned issued permission to conduct a Phase II/III clinical trial of ChAdOx1 nCoV-19 Corona virus vaccine (recombinant) in Form CT-06 bearing No. CT-18/2020 dated 02.08.2020 at various clinical trial sites in the country to determine its safety & immunogenicity.

Whereas, it has been widely reported in the national & international media that the sponsor of the aforesaid vaccine, M/s AstraZeneca PLC has paused the ongoing trial of nCoV-19 Corona virus vaccine (recombinant) as a volunteer developed an unexplained illness. It was further reported that the clinical trial is put on hold across countries where it is conducted i.e. USA, UK, Brazil and South Africa.

Whereas, as per the condition no. 2 of the permission to conduct clinical trial in Form CT-06 bearing No. CT-18/2020 dated 02.08.2020 the clinical data generated in this trial shall be considered along with the data from the AstraZeneca/Oxford clinical trial,

Whereas M/s Serum Institute of India Pvt. Ltd., Pune up till has not informed the Central Licensing Authority regarding pausing the clinical trial carried out by M/s AstraZeneca in other countries & also not submitted causality analysis of the reported serious adverse event with the investigational vaccine for continuation of the Phase II/III clinical trial of the subject vaccine in the country in light of the safety concerns.

In view of the above, I, Dr. V. G. Somani, Drugs Controller General (India) and Central Licensing Authority hereby give you an opportunity to show cause as provided under Rule 30 of the New Drugs and Clinical Trials Rules, 2019, why the permission granted to you in Form CT-06 bearing No. CT-18/2020 dated 02.08.2020 shall not be suspended till patient safety is established. Your reply shall reach undersigned immediately, else it shall be construed that you have no explanation to offer and action deemed fit will be taken against you.

V/s

(Dr. V. G. Somani)
Drugs Controller General (India)

To,
M/s Serum Institute of India Pvt. Ltd.,
212/2, Off. Soli Poonawalla Road,
Hadapsar, Pune 411028.
DCGI directs Serum Institute to suspend any new recruitment in Phase 2, 3 COVID-19 vaccine Clinical Trials

The Drugs Controller General of India (DCGI)- Dr. VG Somani on 11th September ordered the pharma giant Serum Institute of India (SII) to suspend any new recruitment in phase 2 and 3 clinical trials for COVID-19 vaccine till further orders.

This DCGI's orders come soon after Serum Institute submitted their reply to Dr Somani giving an explanation on the show cause notice issued to the drug maker as to why they did not halt the ongoing clinical trial of the ChAdOx1 nCoV-19 corona virus vaccine candidate till doubts about patient safety are cleared.

On 9 September DCGI issued a show-cause notice to Serum Institute for not pausing the ongoing clinical trial of the COVID-19 vaccine.

The apex drug controller issued a show-cause notice after AstraZeneca, which is developing the vaccine candidate against COVID-19 with researchers of Oxford University, paused its trial as a volunteer developed an unexplained illness.

The clinical trial has been put on hold across countries where it was being conducted-- USA, UK, Brazil and South Africa.

In an order issued on Friday the drugs regulator has said: "In the view of the above, I Dr V G Somani, Drugs Controller General of India, Central Licensing Authority, after careful examination of your reply and the recommendations of the Data and Safety Monitoring Board (DSMB) in India, in the exercise of the powers vested under Rule 30 of the New Drugs and Clinical Trials Rules, 2019, direct to you suspend any new recruitment in phase 2 and 3 clinical trials till further orders."

"Increase the safety monitoring of the subjects already vaccinated with the vaccine under trial and submit the plan and report. Submit clearance from DSMB, UK and DSMB, India to obtain clearance from this office prior to the resumption of future recruitment in the trial," read the order.

"You (SII) have submitted your reply to the show cause notice vide your letter dated September 10. In your reply you have stated that DSMB has noted no safety concerns from the Indian study (part 1-phase-2 study) with the first dose and seven days post-vaccination safety data," it read.

Further DSMB recommended 'to pause further enrolment into the study until ongoing investigations of SAE reported in the UK study is completed and the sponsor and the UK DSMB are satisfied that it doesn't pose any safety concern, stated DCGI's order.

On Thursday, Serum Institute of India issued a statement: "We are reviewing the situation and pausing India trials till AstraZeneca restarts the trials. We are following DCGI's instructions."

The country's apex drugs regulator had on August 2 granted permission to SII to conduct a phase II/III clinical trial of ChAdOx1 nCoV-19 coronavirus vaccine (recombinant) at various clinical trial sites in the country to determine its safety and immunogenicity.

Ref. BUSINESSWORLD

*** Trials has been restarted in U.K. on 12.09.2020

Corticosteroid use linked to lower risk of condition worsening in non-ICU patients with COVID-19 pneumonia: Study

A study in PLOS ONE has found that early use of moderate-dose systemic corticosteroids in patients admitted to the general ward with coronavirus disease 2019 (COVID-19) pneumonia complicated by acute hypoxic respiratory failure (AHRF) led to a significantly lower rate of the primary composite outcome of ICU transfer, intubation, or in-hospital death.

The single-center retrospective cohort study led by Monil Majmundar, Department of Internal Medicine, Metropolitan Hospital, New York Medical College, New York, NY, screened 265 patients consecutively admitted to non-ICU wards with laboratory-confirmed COVID-19 pneumonia from March 16 to April 30, 2020. Only the 205 patients who developed AHRF (SpO2/FI O2 ≤ 440 or PaO2/FI O2 ≤ 300) were included in the final study. The mean age was approximately 57 years and 153 (74.63%) were male, while 149 (73.04%) patients were of Hispanic ethnicity/race. Of the 205 patients, 60 (29.27%) received systemic corticosteroids, and 145 (70.73%) did not.

Those in the corticosteroid cohort received systemic corticosteroids in the form of methylprednisolone (n = 29, 48.33%), prednisone (n = 10, 16.67%), hydrocortisone (n = 1, 1.67%),

...
Corticosteroid was started at a median of 2 days (IQR, 1–5) after admission, on a median or equivalent dose of 80 mg per day (IQR, 60–107) of methylprednisolone (equivalent to 12 (IQR, 9–16) mg of dexamethasone) for a median duration of 5 days (IQR, 4–7).

The primary outcome was a composite of ICU transfer, intubation, or in-hospital mortality. Out of 202 eligible patients, 13 (22.41%) in the corticosteroid cohort developed the primary composite outcome, compared to 54 (37.5%) patients in the non-corticosteroid group (P = 0.039). When components of the composite outcome were looked at individually, the adjusted HR for ICU transfer was 0.16 (95% CI, 0.07 to 0.34; P < 0.001), intubation was 0.31 (95% CI, 0.14 to 0.70; P = 0.005), death was 0.53 (95% CI, 0.22 to 1.31; P = 0.172), while the adjusted HR for the composite of death or intubation was 0.31 (95% CI, 0.15 to 0.66; P = 0.002) and discharge was 3.65 (95% CI, 2.20 to 6.06; P<0.001).

The corticosteroid cohort had lower baseline SpO₂/FiO₂ ratios (b = -185.97, P<0.001), but the study found that this increased over time (b = 24.48, P = 0.025), whereas the non-corticosteroid group saw their SpO₂/FiO₂ values decrease over time.

"This study highlights that early administration of moderate-dose of any systemic corticosteroid (oral or intravenous) for a shorter duration in COVID-19 viral pneumonia may not be as harmful as initially suspected, and even more beneficial than shown by the RECOVERY trial," whose early results showed that low-dose (6 mg) dexamethasone cut the risk of death among COVID-19 patients who required oxygen, with or without invasive mechanical ventilation.

They added that "the lower hazard of ICU transfer, intubation, and a higher rate of discharge might be linked to a better quality of life of the patient if corticosteroids are given during the early period of illness. However, data on readmission to hospital or emergency department visits post-discharge would be required to confirm this presumptive role."

The authors said that given the observational design of the study, their findings should be interpreted with caution due to potential bias and residual confounders. They also said that as most of the patients were Hispanic, this limits the generalizability of the study, however it "could be taken as a role of corticosteroid in the predominantly Hispanic population."

Reference: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0238827

SOURCE: PLOS One

Forthcoming event:

World Pharmacists Day celebration
IPA-Bengal Branch
25th September 2020

Theme: “Transforming global health”
Webinar: “Transforming global health”
Time: 7.00 pm

Chief Guest: Dr. T.V.Narayana, National President, IPA
Speaker: Prof. Mahendra G Patel, PhD, FRPharmS, FHEA Alumni Fellow NICE National Board Member of the Royal Pharmaceutical Society, UK

Other events: Poster & Essay competition

Reader's Column

Dear Editor,

Thank you very much for providing us information on medicines, healthcare, professional news constantly for more than 13 years without fail.

This helps us immensely to discharge our duties in different settings of health care.

Regards.

D. Murthy