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Covid -19 Pandemic and Oncology Clinical Trials: Our Experience

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I. INTRODUCTION

The Covid-19 Pandemic is impacting every facet of our global and domestic societies and healthcare system in an unprecedented form. Responding quickly and confidently to the Covid -19 crisis is the healthcare challenge of our generation. Our overreaching goal is to keep our Cancer patients and staff safe while continuing to provide compassionate, high quality care under circumstances we have never had to face before.

Our hospital is a Comprehensive Care Cancer Hospital, located in Rural part of Western India. Since last 20 years we are providing affordableCancer treatment to patients of Gujarat and theneighbouring states of Madhya Pradesh, Rajasthan and Maharashtra.

Our Clinical Research Department is conducting Oncology Clinical Trials since 2008 and we are a USFDA approved site for conducting BA/BE studies. Also, our Institutional Ethics Committee is NABH accredited..

When the nationwide lockdown was announced from 24th March 2020by our Prime Minister, we had 8 Oncology trials ongoing at our Hospital. This involved patients of Lung, Breast, Head & Neck Cancer and Lymphoma.

We all know that delay in treatment of Cancer patients leads to poor prognosis and affects overall survival. The challenges that we faced during the initial days of lock down was to set the balance right between the need to continue cancer treatment and to ensure safety of patient and staff.

As the Hospital management was working on formulating the guidelines during the first week of lockdown we deferred the dosing of patients for 1 week ie from24th march to 31 st March . During this period we made a list of all patients who would require dosing during the lockdown period. Meanwhile research departmentSOPs for screening, utilization of PPE, social distancing and hand hygiene were formulated and training to all health care providers was imparted.

In the Hospital all patients are screened for symptoms as soon as they enter the Cancer centre and also each step along the way. History regarding fever, cough any contact with anyone having who has Covid-19 is taken. All Vitals are checked, the PI and Research team meet the subject and patient is admitted as per protocol or Oral IP is dispensed as case may be.

The Clinical Research Department also laid down its guidelines for conducting studies during the

. The IEC members were informed that new subjects would be enrolled in any of the active studies, however the dosing of the ongoing patients for the clinical trials would continue Lockdown:

- Initiation of new projects: Although three clinical trial projects were approved by the Institutional Ethics Committee, the Site Initiation Visit was not performed by the Sponsor because of lockdown. Thus, these projects which were proposed to be initiated during the lockdown period were postponed.
- Enrollment/recruitment of the patient: At the site eight clinical trials for different indications were active for recruitment but no new subject were recruited as per the guidelines provided by the Hospital. We continued treatment and dosing of 31 patients on the different oncology trials but did not recruit any new patients.during the lockdown period from 24th March to 31st May 2020. A total of 25 Chemotherapy dosing was done.
- Managing Patient visit schedule: Scheduled visits were carried out by the Clinical Research Coordinators in accordance with the Hospital advisory. The Clinical research coordinators were called on alternate days. From March 24th to 31st March patients were not called for their scheduled visit. But from 1st Aril, 2020 onwards visits for all the patients were scheduled in consultation with the sponsor and Head of the Department of clinical research, KCHRC and the subject were contacted to visit the hospital.

Activities performed and challenges faced by the site:

- Maintaining the timelines as per the study protocol: It was difficult to maintain the timelines as per the study protocol. There was excursion beyond the window period as per the protocol in about 25% of the patient.

- Dosing: During the period of Lockdown, 25 Chemotherapy dosings were scheduled, our site completed 75% of the dosing in a scheduled time-period without any excursion.
- Follow up visits and End of Treatment: Follow up visits in 50% of cases were performed without any deviation but in the rest excursion of few days to few weeks occurred.
- Challenges:
  - Transportation: Commuting of trial subjects to the hospital was one of the main concerns. All Public transport facilities had ceased and patients had to hire private vehicles. Even travel from different districts or different state was rendered difficult due to the closure of all the borders. Following measures were taken to ensure the timely visit by the hospital administration and Clinical research staff:
  - providing a letter of treatment to all the patient participating in the trial via WhatsApp or Email.
  - Assisting them with transportation. Reimbursing them the travel cost.
  - Assisting patient in getting permission from government official/Collector office.
- Interaction with the IEC/IRB:The Head of Research Department continuously updated all Ethics Committee members about the status of the trial and the trial subjectsas per schedule from 1 st April 2020. As per the addendum of the IEC, all the notification to the IEC were done via email.
- The main focus of the Ethics Committee was the safety of trial subjects and the medical staff, risk benefit analysis for patients in ongoing trials, administration of Investigational Product (IP) and any deviations from Protocol.

IEC had announced a meeting on 28th March 2020 before lockdown, which was postponed and finally was carried out on 09th May 2020 through Zoom. In the meeting one Sponsored study , one amendment and two Academic Multicentic Clinical trials were discussed and approved. The meeting was recorded and was archived.
All the Institutional Ethics Committee activities were carried in accordance to National Guidelines for Ethics Committee Reviewing Biomedical and Health Research during Covid -19 Pandemic which was published by the ICMR on April2020.

II. CONCLUSION

The Pandemic has fundamentally changed many aspects of our lives and we have to learn how to adjust to the new realities of how we work and engage with our trial subjects. This is at the top of our mind as we come together with a common goal to keep looking for new ways to support cancer patients as their needs evolve. As Oncologists we have to balance the need to continue cancer treatment and relevant Clinical Trials as before and to ensure safety of patients and employees.