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EC DIABETES AND METABOLIC RESEARCH

Review Article

Managing Type 2 Diabetes Clinical Trial at Site Amidst *Coronavirus* Outbreak

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Abstract

COVID-19 has posed myriads of challenges due to lockdown, travel restrictions, quarantine and social distancing. The clinical research companies across the globe were scrambling to mitigate its implications on clinical trials. Some of the impacts were immediate which have a cascading effect on protocol compliance, efficacy and data integrity. The primary concern was the safety of the patients under clinical trials. There was an increased patient hesitancy to visit trial facilities leading to huge patient dropout. There was a contamination risk between patients, sites and the community. The integrity of trials was also threatened. In this article, we have highlighted the solutions to these challenges while managing type 2 diabetes clinical trial at site.

Keywords: *Clinical Trials; Type 2 Diabetes; Challenges; COVID-19*

Introduction

A novel *coronavirus* outbreak, with its epicentre in Wuhan, China, has emerged as an international public health emergency [1] caused by severe acute respiratory syndrome [2]. COVID-19 has posed a very challenging situation in India, as the whole country was under national lockdown and it has affected all segments of society including healthcare [3] and clinical trials. COVID-19 pandemic also led to a decline in accessibility to hospitals and clinics as most of them pulled themselves off services [4].

Several concerns emerged about how to handle clinical trials operations under national lockdown due to restriction of movement and the main obstacle was to perform on site patient visits. This untoward incident had severely affected the day to day operation of ongoing clinical trials. As a result, several approaches have been implemented at site to keep trial alive keeping in mind that rights, safety and well-being of trial subjects is paramount to us [5].

In this review, our aim was to explain the impact of the lockdown in response to the COVID-19 pandemic on type 2 diabetes (T2DM) clinical trial conducted at Department of Medicine, Maulana Azad Medical College, New Delhi, India.

Strategies adopted

Study site has faced multiple barriers to tackle COVID-19 pandemic including study drug stability issues, restricted access due to COVID-19 dedicated hospital, skeleton research staff, investigator's engagement in COVID-19, rapidly changing guidelines and procedures to combat the spread of the virus [6].

Multiple strategies have been adopted to mitigate the impact of COVID-19 on T2DM clinical trial at site. Physical visits to the site were converted into phone visit [7]. Adverse event, technical complaint, concomitant medication, assessment of COVID-19 symptoms if any, were done through phone in consultation with Principal Investigator or Sub-Investigator. Along with Principal Investigator and Sub-Investigator, site staff also contacted the subject on a regular basis to monitor more stringently about their health. As all the subjects were type 2 diabetic so they were also counselled telephonically for healthy diet. Subject were advised to continue taking standard of care along with investigational product. Out Patient Departments (OPDs) were not operational from where patients were getting medicines free of cost hence they were also instructed to purchase medicine from nearby medical stores so that they should not stop background medications.

To ensure the uninterrupted supply of Investigational Medicinal Products (IMP) and ancillary supplies e-pass were issued to the subject or subject's attendant so that they can visit the site, to collect IMP or ancillary supplies, if mutually agreed. IMP dispensing was done outside the hotel premises to ensure the safety of patients as hospital was not safe and they could catch COVID-19 infection.

One of the main areas of concern which requires immediate attention was the delivery of Investigational Medicinal Products (IMP) to subjects who need them. Various alternative dispensing methods were incorporated to deal with this crisis like shipment of IMP through appointed substitute, site staff or through approved courier services where subject's confidentiality was maintained according to the law of land (Figure 1).

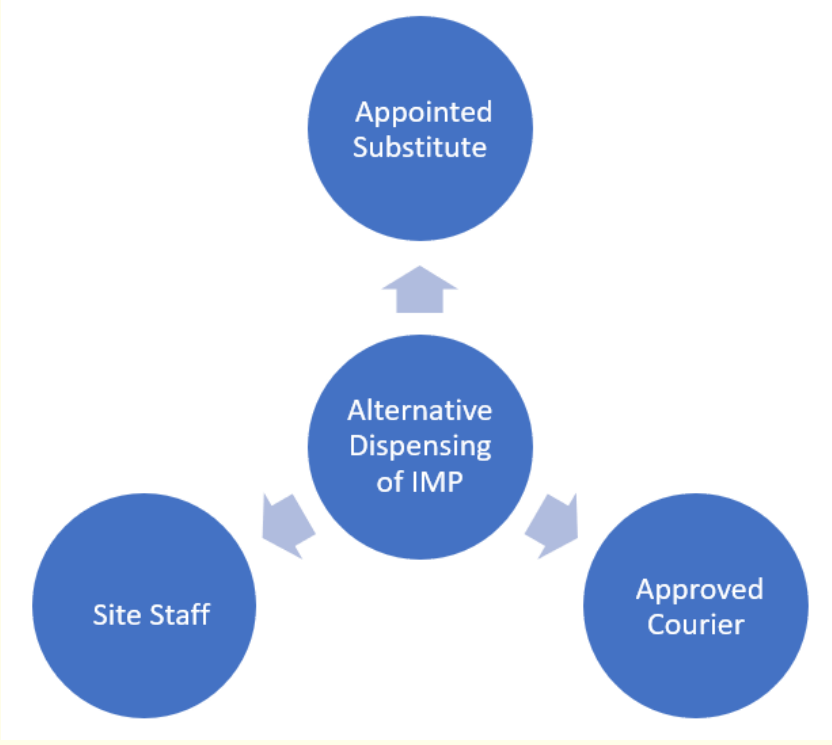

Figure 1: *Alternative methods of dispensing investigational medicinal products to trial subjects.*

Recent technologies have improved our skills to monitor the temperature of stored IMP at site efficiently and accurately. Temperature monitoring of IMP was done through automated device which record temperature automatically. As per site policy before every IMP dispensing, temperature was checked just to ensure that no unreported temperature deviation occurred in between and clinical trial products are safe for dispensing.

All communications with the Ethics Committee (EC) were done through email. The electronic versions of documents were sent to EC through email for their review and approval [8]. EC meetings were conducted through webinar to discuss any urgent issue like reporting of Serious Adverse Event (SAE).

During COVID-19 pandemic normal people being exposed to extraordinary situations which created global panic so research subjects may also have significant and variable impact for the same hence psychological counselling was also provided to subject for their well-being.

Patients were also counselled on a regular basis to follow COVID-19 advisory issued by the Ministry of Health, Government of India to protect ourselves and prevent the spread of this deadly pandemic. These include but are not limited to social distancing, wearing of mask, hand hygiene, respiratory hygiene, stay at home guidelines unless there is an emergency [9]. They were instructed that If you experience fever, cough, breathing problem or any other illness contact site team immediately to seek medical advice.

Discussion

To keep our patients safe during COVID-19 outbreak was the top priority for site. In line with the recommendations from Central Drugs Standard Control Organization (India's regulatory body) which recommended that safety and well-being of trial patient is a significant priority [10] site has followed all guidelines to safeguard the interest of patient.

Institutional Ethics Committee has also made several provisions to tackle this unpredicted situation. Departmental Standard Operating Procedures (SOP) was also implemented to lower the impact of COVID-19 and to safeguard patient health.

Coronavirus was an immediate threat to people's health, so it was prudent to make the necessary changes to the protocol and study design to deal with this crisis. Proper documentation was maintained for each and every activity. Site personnel safety was also maintained which include proper sanitization and restricted movement at research building, wearing of gloves, mask and other protective gears. Effective planning and active management has reduce, the impact of COVID-19 to some degree.

We have shifted from a site-centered approach which was based on routine clinic visits to online approaches where each stage has been remotely monitored, controlled and trialled through phone or email, complying all clinical protocols and applicable guidelines.

Conclusion

Amidst *coronavirus* outbreak various clinical trial activities were skipped as the whole country was under national lockdown, which posed a big challenge towards the subject's physical visit at site. The best part was that no patient was running short of IMP and ancillary supplies and its compliance was also maintained along with integrity of clinical data by maintaining its complete record. Now the time has come to adopt alternative and innovative approaches in clinical trials to address the inevitable threats such as COVID-19.

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Disclosure Statement

All authors declare that they have no conflict of interest.

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