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Follow-up in Clinical Trials of Anti-tumor Drugs after the Normalization of COVID-19's Prevention and Control: An Investigation Study

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Abstract

Background and Objective: After May 2020, the prevention and control of COVID-19 in China has entered precision and normalization period, and sporadic cases appear everywhere. Under these circumstances, we ensure the safety of subjects and their trial drug treatment based on scientific big data and practical measure. At last, most subjects completed the clinical trial drug treatment and data collected according to the protocol, and COVID-19 did not have a significant impact on clinical trials.

Methods: The number of new COVID-19 cases per month in China, and subjects visiting on site, mailing drugs, delayed visiting and new enrolled per month in Department of Renal Cancer and Melanoma, Peking University Cancer Hospital were collected from May 2020 to October 2021. The correlation between the number of COVID-19 new cases and the other four items was analyzed.

Results: The number of increased COVID-19 cases in China fluctuated every month, followed by the number of subjects mailing drugs and delayed visiting in Department of Renal Cancer and Melanoma. The correlation coefficients are 0.690 and 0.624 respectively (P<0.05). The number of subjects visiting on site and new enrolled increased in fluctuation, which has no obvious correlation with the increased COVID-19 cases. From May 2020 to October 2021, the number of subjects visiting on site was 8366 (98.35%) and 0 subjects withdrew from clinical trials.

Conclusion: Relying on scientific big data and practical measures, subjects' visiting on Department of Renal Cancer and Melanoma and enrolling didn't affect by COVID-19 greatly. The number of drug mailing and delayed visiting accounted for small proportion. The data collection is effective, and COVID-19 will not have a significant impact on clinical trials carried out in Department of Renal Cancer and Melanoma.

Keywords: Clinical trials; Subjects; Follow-up; COVID-19; Investigation

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Background

The global epidemic of COVID-19 is still spreading and may exist for a long time. In China, since the end of April 2020, we have entered the stage of regular COVID-19 prevention and control, and from August 2021, has entered the stage of "dynamic zero-out" of full-chain precise prevention and control [1-4]. The goal at this stage is to minimize the occurrence of the epidemic, effectively deal with sporadic cases and clusters after the outbreak, basically control the epidemic within one incubation period (14 days), and strive to achieve the maximum effect of prevention and control with the minimum social cost [1]. Its scientific connotation mainly includes: (1) Through fever clinic, health monitoring, nucleic acid testing, screening and other means, timely detection of cases and infected persons, isolation and treatment of the source of infection. (2) Using epidemiological surveys, big data and other information technologies to quickly identify and control the epidemic point or area, conduct precise management of close contacts and at-risk groups, implement public health and social interventions such as crowd reduction, cut off possible transmission routes and protect vulnerable groups. (3) Prevent disease progression and reduce severe illness and death through effective treatment of patients. (4) "Dynamic zero Clearance" pursues fast and accurate, rather than "zero infection", and maximizes the coordination between epidemic prevention and

control and social and economic development [1].

China's GCP, published as early as 2003, stipulated that investigators must understand the protocol in detail and strictly follow it [5]. As subjects who receive trial drug treatment and to be evaluated for the efficacy of the clinical trial [6], it is of vital importance to ensure the quality of clinical trials for the subjects to visit on schedule, do relevant examinations, receive trial drug treatment and complete trial data collection according to the protocol.

In the case of the public health event of the epidemic, it is a challenge to ensure the safety of subjects while ensuring their clinical trial drug treatment, so as to ensure the integrity of clinical trial data collection.

Methods

Log in to the official website of National Health Commission of the People's Republic of China (nhc.gov.cn) and count the monthly number of new COVID-19 patients notified on the official website of China from May 2020 to October 2021, and count the monthly number of subjects visiting on Department of Renal Cancer and Melanoma, the monthly number of subjects mailed drugs from this department, the monthly number of subjects postponed visits, and the monthly number of new patients enrolled in this department during this period.

Data analysis

The data were input into EXCEL to calculate the total number of new COVID-19 cases from May 2020 to October 2021, the total number of subjects visiting on site, the times of mailing drugs, the times of delayed visits, and the total number of new patients enrolled in this department. Charts were used to show the changing trend of each data. SPSS 24.0 was used to analyze the correlation between the number trend of new COVID-19 cases and the other four items' trends.

Results and Discussion

None of the subjects who visited on the department contracted COVID-19, which is due to our series of epidemic prevention measures. First of all, the subjects and we, as medical staff, should abide by the national and regional epidemic prevention policies and the management measures formulated by the infectious diseases department of our hospital. For example, subjects who come to the hospital should fill in the epidemiological survey form and show their health code and travel code. Secondly, as a research nurse, she must pay close attention to the new COVID-19 cases and new medium-high risk areas every day. Then, for the subjects from the villages, counties

Chart 1: The trend of mailing drugs, delayed visiting, new enrolled subjects.

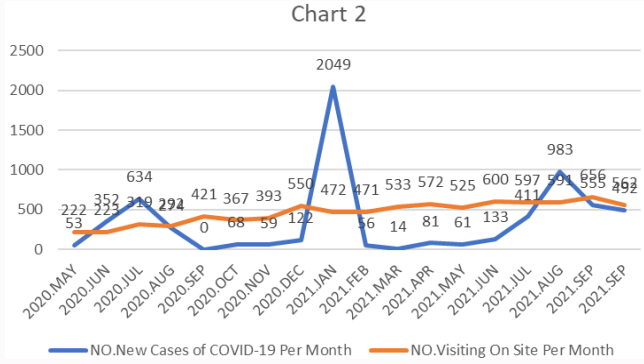

Chart 2: The trend of new cases of COVID-19 and subjects visiting on site.

and cities with COVID-19 cases, the research nurse will confirm further personal information, such as: Mode of transportation to the hospital, self-driving, by train or by plane; Areas visited and people contacted in the past 14 days; Nucleic acid test reports of the local and our hospital; Distance between the place of residence and the area with cases.

During 2020 and 2021, has there were 49 anti-tumor drug clinical trials in our department with the frequency of Q1W, Q2W, Q3W or Q4W. Drug administration include oral drugs, intravenous drugs, oral and intravenous combined administration, and subcutaneous injection. From May 2020 to October 2021, the number of subjects visiting on site was 8,366 (98.35%), and the number of mailing trial drugs, delaying visits due to the epidemic, and new patients enrolled were 33, 107, and 575 respectively (Table 1). During this period, no subjects withdrew from the clinical trials due to the epidemic, and all subjects who visited on site completed the data collection according to protocol.

As can see from the trend chart, as the monthly number of new COVID-19 cases fluctuated, the monthly number of mailing drugs and the number of subjects delaying visits also fluctuated (Chart 1). The two were correlated, and Pearson's correlation was 0.690 and 0.624 respectively, with p values less than 0.05 (Table 2). During this period, the number of subjects who visited on site each month and the number of newly enrolled subjects each month increased with fluctuations (Chart 2), which was not significantly correlated with the number of new COVID-19 cases each month. Pearson's correlation coefficients were 0.122 and 0.111 respectively, with P values greater than 0.05 (Table 2).

The number of clinical trials of new anti-cancer drug in our hospital increased year by year, from 187 in 2016 to 637 in 2020, and more than 30 new anti-tumor drugs on the market were led or participated by our hospital. A survey in 2019 showed that 89.4% of patients in cancer hospitals had heard of clinical trial, and 74.5% were willing to participate in clinical research, showing a high degree of awareness and willingness to participate [7], which was improved compared with the survey results in 2017 and 2011 [8,9]. The marketing of new cancer drugs has brought new hope to cancer patients, and at the same time, more cancer patients know about the clinical research of new anti-cancer drugs, and it is possible to obtain new treatment methods.

The outbreak of COVID-19 in early 2020 had a certain impact on the follow-up of clinical trial subjects in a short period of time [10], but the shift of epidemic prevention and control strategy based on

Table 1: The results of the investigation.

Time Slot	NO. new cases of COVID-19 per month	NO. visiting on site per month	NO. mailing drugs per month	NO. delayed visiting per month	NO. new enrolled per month
2020. MAY	53	222	1	8	16
2020. JUN	352	223	3	8	35
2020. JUL	634	319	3	4	27
2020. AUG	274	292	1	3	28
2020. SEP	0	421	1	3	47
2020. OCT	68	367	1	2	27
2020. NOV	59	393	0	6	29
2020. DEC	122	550	4	2	48
2021. JAN	2049	472	7	15	29
2021. FEB	56	471	4	10	16
2021. MAR	14	533	1	7	22
2021. APR	81	572	1	6	41
2021. MAY	61	525	0	4	24
2021. JUN	133	600	1	5	31
2021. JUL	411	597	1	2	34
2021. AUG	983	591	2	7	42
2021. SEP	555	656	1	7	38
2021. SEP	492	562	1	8	41
TOTAL	6397	8366	33	107	575

Table 2: The Pearson's correlation between new COVID-19 and the other four items.

	New COVID-19	P value
Visiting on site	0.122	0.629
New enrolled	0.111	0.66
Mailing drugs	0.69	0.002
Delayed visit	0.624	0.006

the reality and the national economy and people's livelihood, from "an epidemic emergency containment phase" to "the normalization stage of COVID-19's prevention and control ", "whole chain precision control of dynamic zero phase" [1], make this influence gradually fade away. Because subjects know how to protect themselves in daily life, and the national epidemic prevention information is transparent, subjects can quickly learn about the current situation of the epidemic in a certain place and make appropriate adjustments to their travel and treatment.

Hospitals and sponsors have also actively developed clinical trial management measures under the epidemic situation. For example, in multi-center clinical trials, subjects are allowed to undergo safety checks at local centers, and investigator make evaluation based on local data and use more media measures, such as internet video, to determine whether to continue the treatment. If there is no clinical trial center in the local area, but there are experimental drugs on the market, they can purchase locally for use and reimbursed; for oral drug trial, those who cannot come to the hospital due to local epidemic policy can do examination in the local class A hospital and be given drugs by mail. If subjects do not meet the above conditions, the visit can only be postponed, but China's current "dynamic zero-clearance" policy, that is, one incubation period (14 days) to control the epidemic, so that the delayed visit of subjects accounted for only 1.3%. In addition, the sponsor will reimburse the possible isolation costs of the subjects, and also accept the examination results from other hospitals and the results can input EDC to analyze, etc.

A series of epidemic prevention and clinical trial management measures under the epidemic ensured trial treatment for most subjects and the integrity of clinical trial data collection.

Conclusion

It is of vital importance to ensure the safety and treatment of subjects as the normalization of COVID-19's prevention and control. However, based on scientific data and practical measures, the number of subjects visiting on site and newly enrolled subjects did not have a significant impact in our department due to the epidemic situation, and the number of drug mailing and delayed visiting caused by the epidemic was relatively small. Therefore, the collection of clinical trial data was effective and had no significant impact on the overall clinical trial.

Implications for Practice and Limitations

This study investigated and analyzed the impact of COVID-19 on clinical trials carried out in our department and how we can respond scientifically to an acute public health emergency. As China's epidemic has entered the normal stage of precise prevention and control, we are becoming more and more confident in the management of subjects and the quality assurance of clinical trials.

Nevertheless, this survey was only conducted in the Department of Renal Cancer and Melanoma and did not include all the clinical trials in our hospital. Although the result represents part of the situation of our hospital, it cannot reflect the actual visits of the whole hospital and other clinical trials across the country.

At present, the international epidemic situation is still in the period of pandemic. As the virus continues to mutate and spread faster, China ushered in new challenges in epidemic prevention

and control at the beginning of 2022. In follow-up studies, further attention should be paid to the impact of the epidemic situation on clinical trials. In addition to epidemic prevention, the quality of clinical trials should be ensured to avoid the impact of repeated outbreaks on the overall clinical trials.

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