

Status and Analysis of 832 Investigator-Initiated Coronavirus-Related Clinical Studies

Yurong Zhang¹, Li Wang^{1*}, Ruizhong Wang², Zhang Qi³, Rui Xu¹

¹Department of Clinical Pharmaceutical Research Institution, the First Affiliated Hospital of Xi'an Medical University, Xi'an 710077, Shaanxi Province, China

²Department of Pharmacy, The First Affiliated Hospital of Xi'an Medical University, Xi'an 710077, Shaanxi Province, China

³Shaanxi Center for Drug and Vaccine Inspection, Xi'an 710065, Shaanxi Province, China

*Corresponding author: Li Wang, 394004312@qq.com

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Abstract: *Objective:* To contribute to the development of clinical research on novel coronavirus by analyzing the clinical research data of COVID-19. *Methods:* Searches were performed on the database of “National Health Insurance Information Platform Medical Research Registration Information System” using the keywords “COVID-19” and “Novel coronavirus.” The search was performed till 31 December 2022. This paper presents a statistical analysis of the status quo of the registered projects in terms of the number of registered projects, the types of projects, the levels of the institutions, the types of research, the intervention measures, the research design, the main objectives of the research, and so on. *Results:* A total of 823 investigator-initiated clinical studies of COVID-19 were documented, and the number of studies registered peaked on December 31, 2020, and December 31, 2022. Among them, there were 819 items from general medical research (99.5%), 812 items from medical institutions (98.7%), and 713 items from Medical Grade III, and Class A hospitals (86.6%). Among these items, 534 (64.9%) were observational studies. The most common intervention method used was administering existing drugs, with 140 studies utilizing them. This data analysis also included 128 case-control studies and 247 treatment-oriented studies. *Conclusion:* Researchers in local medical institutions have been actively carrying out clinical research related to COVID-19. However, they should refer to registered research to avoid duplicate research.

Keywords: Investigator-initiated; Clinical research; COVID-19; Data analysis

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1. Introduction

The COVID-19 infection has been prevalent in many regions of the world for more than three years, threatening human health and affecting social and economic development. Medical personnel in medical institutions involved on the frontline of the pandemic have also carried out a number of investigator-initiated clinical studies on COVID-19 ^[1]. On September 9, 2021, the National Health Commission of the People's Republic of China issued the “Management Measures for Investigator-initiated Clinical Research by Medical and Health Institutions (Trial)” (hereinafter referred to as “management measures”), which clearly requires that

clinical studies approved by medical and health institutions shall be uploaded in the “National Health Security Information Platform” hereinafter referred to as “the system”) as required. As of December 31, 2022, a total of 823 relevant investigator-initiated clinical studies in China have been recorded on the system. The clinical studies were sorted out and analyzed, and the archival clinical studies were classified and analyzed in multiple dimensions, so as to contribute to the development of clinical studies on COVID-19 and medical ethics issues.

2. Data and method

A search was performed on the system, with the keywords “COVID-19” and “novel coronavirus” to obtain investigator-initiated clinical studies on COVID-19 in China as of December 31, 2022. The COVID-19 clinical studies were extracted based on several aspects, including type of project or institution, level of institution, the type of study, intervention measures, study design, main objectives, etc. Statistical analysis was performed using Microsoft Excel.

3. Result

3.1. Number of clinical research records

Since September 3, 2020, when the records of three COVID-19 clinical studies initiated by researchers at the Fifth People’s Hospital of Anyang City began, up to December 31, 2022, a total of 823 clinical studies have been documented in the system. By analyzing the relationship between the period of clinical research filing and the volume of filing in half a year (**Figure 1**), it can be seen that the number of clinical studies peaked on December 31, 2020, and December 31, 2022.

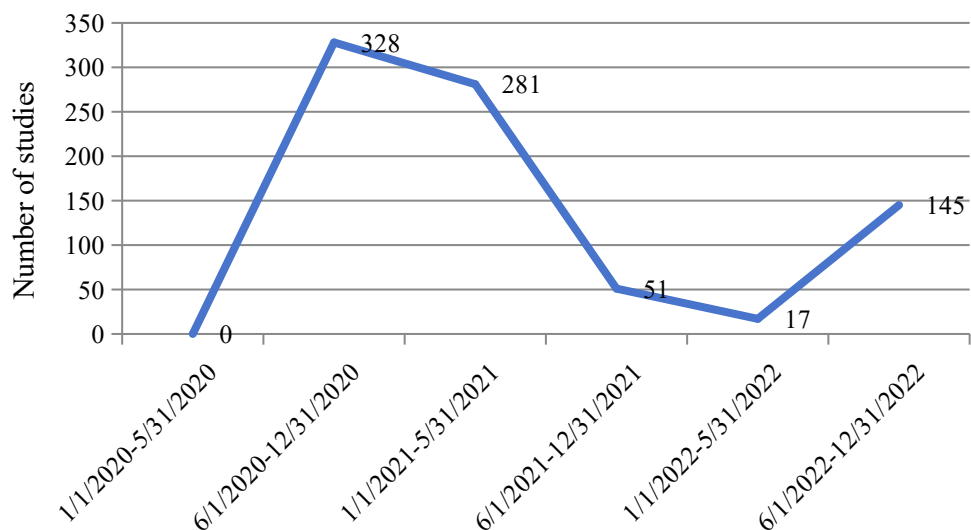


Figure 1. Number of records for investigator-initiated clinical research projects in different periods (half a year)

Of the 823 clinical studies on COVID-19 that have been filed, 819 (99.5%) were general medical research projects and 4 (0.5%) were stem cell medical research projects. Among the types of institutions recorded, 812 were medical institutions (98.7%), 11 were disease control and prevention centers (1.3%), and 0 blood transfusion services or maternity and child care institutions. As for the institutional levels, 713 (86.6%) were

Grade III Class A hospitals, 14 (1.7%) were Grade III Class B hospitals, 62 (7.5%) were Grade II Class A hospitals, 18 (2.2%) were Grade II Class B hospitals, 1 (0.1%) were Grade II hospitals, 1 (0.1%) were Grade I hospitals, and 14 were unrated (1.7%), as shown in **Table 1**.

Table 1. Investigator-initiated clinical research projects on COVID-19

	Category	Quantity
Project type	Stem cell medical research project	4
	Somatic medicine research project	0
	General medical research project	819
Organization type	Medical institution	812
	Disease control and prevention center	11
	Blood transfusion services	0
	Maternity and child care institution	0
	Others	0
Hospital grade	Grade III Class A	713
	Grade III Class B	14
	Grade III	62
	Grade II Class A	18
	Grade II Class B	1
	Grade II Class C	0
	Grade II	1
	Grade I Class A	0
	Grade I Class B	0
	Grade I Class C	0
	Grade I	0
	Unrated	14

3.2. Analysis of research types

In terms of study type, 534 (64.9%) were observational studies, 204 (24.8%) were interventional studies, and 85 (10.3%) were blank (unknown), as shown in **Figure 2**.

3.3. Analysis of intervention measures

Additional statistics for the clinical research interventions, as depicted in **Figure 3**, reveal a wide range of interventions. These interventions encompass listed drugs, non-listed drugs, behavioral and lifestyle modifications, listed medical devices, surgical procedures, non-listed medical devices, clinical treatment plans, biomedical technologies, psychotherapy, stem cell clinical research, group health management measures, physical therapy, dietary supplements, and more. Among these, there were 140 studies involving listed drugs.

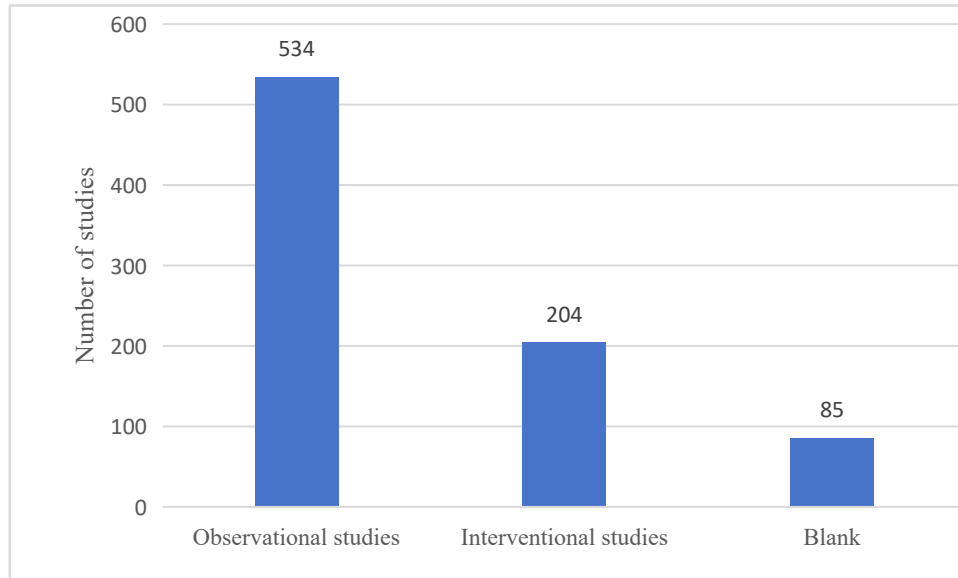


Figure 2. Analysis of types of investigator-initiated COVID-19 clinical research projects

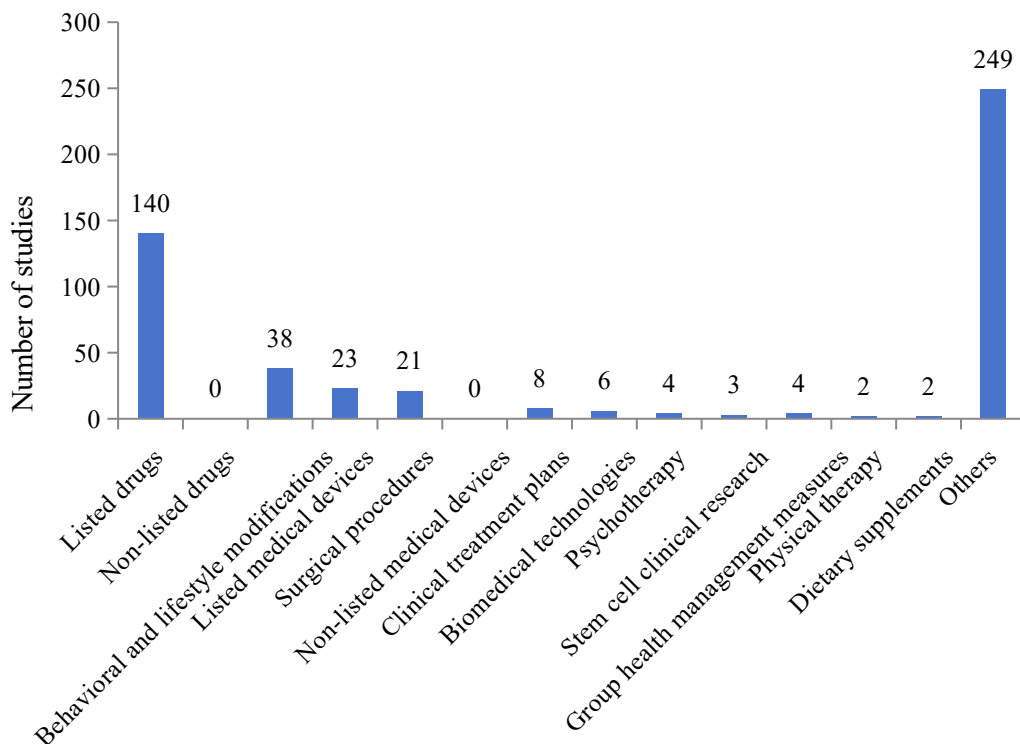


Figure 3. Analysis of intervention measures

3.4. Research design analysis

As shown in **Figure 4**, the study design in archival clinical studies included cross-sectional studies, case-control studies, cohort studies, diagnostic tests, case report forms or case series studies, randomized controlled studies, single-arm studies, non-randomized concurrent controlled studies, and others. Among the other types of studies (310), the top three types were case-control studies (128), cross-sectional studies (117), and cohort studies (104).

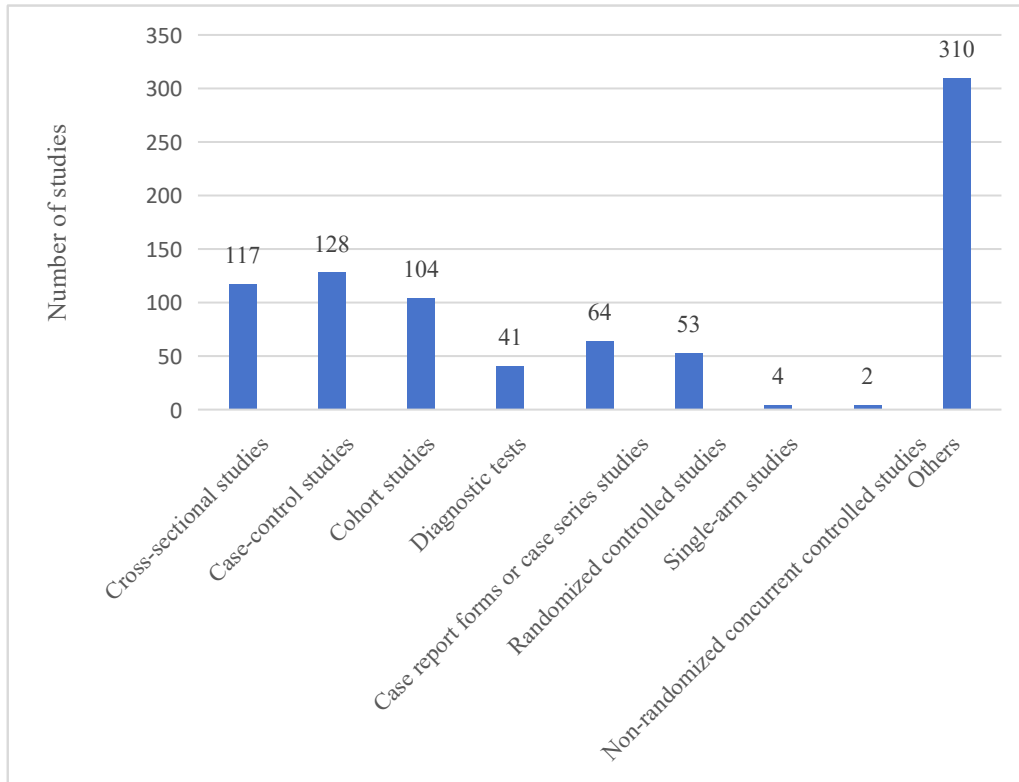


Figure 4. Analysis of the study design for the investigator-initiated COVID-19 clinical research projects

3.5. Analysis of main objectives

Among the 823 investigator-initiated clinical research projects, the main objectives of the studies were extracted (Figure 5). The objectives included treatment, diagnosis, prevention, screening, prognosis, basic research, and others, with treatment being the most common objective (247).

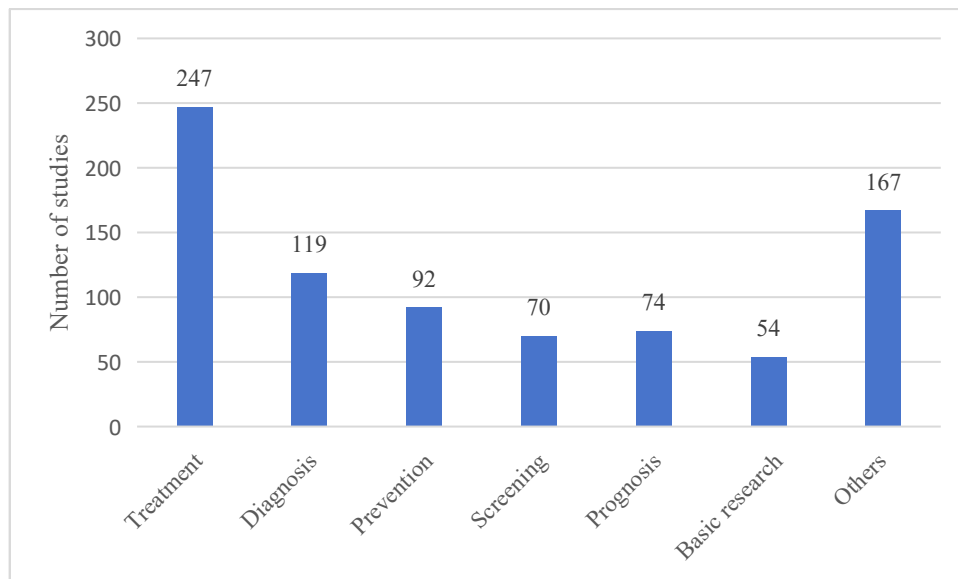


Figure 5. Analysis of the study design for the investigator-initiated COVID-19 clinical research projects

4. Discussion

4.1. Extensive clinical research

Since the outbreak of COVID-19 in December 2019, it has exhibited strong infectivity and widespread transmission. At that time, there was no specific treatment or vaccine for this disease ^[2]. Therefore, a large number of clinical studies were carried out on COVID-19 to find safe and effective drugs for the disease. The management measures also stated that clinical research needs to be disclosed to the public by registering them to a platform created by the National Health Commission to avoid the repetition of similar research, leading to the waste of medical resources. The number of studies carried out peaked at December 31, 2020, and December 31, 2022

Through our analysis, it was found that the investigator-initiated studies on COVID-19 were mainly observational, and they were mostly done in Grade III hospitals, as those hospitals are rich in resources and manpower ^[3].

4.2. Clinical study design

Clinical study design plays a crucial role in the process of clinical trials. Randomized controlled studies, considered high-level sources of evidence-based medical data, are the most reliable research designs for assessing the causal relationship between interventions and outcomes ^[4]. Observational studies have a lower level of evidence compared to randomized controlled studies. However, with the vigorous development of clinical research, observational studies are gaining increasing importance ^[5]. This study also found that the majority of observational studies were case-control studies (128), cross-sectional studies (117), and cohort studies (104).

Clinical studies are designed based on professional clinical expertise and with a focus on the ethical considerations of ensuring the safety and well-being of study subjects ^[6]. Studies have shown that only 23.51% of researchers fully consider ethical factors when designing their research protocols ^[7]. When ethical considerations are not incorporated into the design of clinical studies, and the study protocol is imperfect, there may be potential risks to the study subjects. Therefore, filing becomes a necessary measure for the ethical oversight of clinical research, as it can help standardize the ethical review of clinical studies to a certain extent.

4.3. Intervention measures

Statistical analysis showed that listed drugs were the main intervention methods used in investigator-initiated clinical studies on COVID-19, with a total of 140 studies using them.

Certain recorded projects indicate a shift in the scientific research mindset of medical professionals. These studies not only focused on the disease itself but also encompassed psychological treatment, group health measures, dietary supplements, and other intervention research aimed at various groups.

There are still shortcomings in this study. Although we have carried out some sorting and statistical analysis, we are only limited to the preliminary analysis of data and have not conducted further research on each item. In the face of COVID-19 infection, medical staff in medical institutions have pooled their wisdom, overcome scientific research difficulties, and carried out various clinical studies to provide certain data support for the prevention and treatment of COVID-19. It is also a great challenge to all medical institutions. Only by reviewing the scientific nature and taking into account the normative ethics, can the two-pronged research break through the research on the prevention and treatment of sudden infectious diseases ^[8].

Author contributions

Conceptualization: Yurong Zhang

Resources: Rui Xu, Qi Zhang

Writing-original draft: Yurong Zhang

Writing-review and editing: Li Wang

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Disclosure statement

The authors declare no conflict of interest.

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