

RE-INFECTION AND SIDE EFFECTS AFTER COVID-19 VACCINATION: A CROSS-SECTIONAL STUDY FROM IRAN

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ABSTRACT

BACKGROUND:

The effectiveness of vaccination as one of the management strategies of the COVID-19 pandemic should be investigated and its results should be considered as a lesson learned in facing future crises.

OBJECTIVES:

This study was conducted determining the rate of reinfection with COVID-19 after vaccination and the side effects of vaccination.

METHODS:

In this cross-sectional descriptive study, 351 employees who had undergone corona vaccination were examined by available a random sampling method. To collect data, a personal profile form and a researcher-made questionnaire were used.

RESULTS:

About 42% of the employees were infected before the injection of the vaccine, and the rate of COVID-19 after the injection of the first dose, the second dose and the booster dose was 16%, 19.1% and 14.8% respectively. 24% of the samples did not report any side effects after the vaccine injection, but other people reported the most common side effects as "fever and sweating" (42.5%), "weakness" (38.5%), "headache" (33.6%) and "injection site pain (32.8%)" reported.

CONCLUSIONS:

The main side effects reported were general symptoms and the body's response to the corona vaccine injection, which is the case for many other common disease vaccines. But the remarkable thing about the reported side effects is that the frequency of common side effects reported in the third dose has decreased compared to the first and second doses.

KEYWORDS

Vaccination, Re-infection, COVID-19, Side effects

INTRODUCTION

The COVID-19 pandemic, since its onset in December 2019, has created various challenges for the public and healthcare providers. Challenges such as significant mortality, lack of recognition of the disease and how to deal with it, lack of personal protective equipment etc [1-4].

Among all the damages caused by this pandemic, it can be said that the high death rate in different countries during the periods of this pandemic was the most important and severe of these damages [5, 6]. According to the latest reports, the death rate due to infection with COVID-19 in the world [7] and in Iran [8] has been 6,946,336 and 146,580, respectively, since the beginning of the pandemic until December 2023.

In order to control the COVID-19 pandemic, various strategies were implemented, such as complete quarantine of cities, social restrictions, physical distancing, use of personal protective equipment, etc [5, 9]. The most effective strategy to control this pandemic was the production of the COVID-19 vaccine and the national vaccination program [6, 10, 11]. Vaccination programs in some developed countries started and continued at a higher rate compared to developing and underdeveloped countries [10, 12]. The result of this vaccination program was a significant reduction in the rate of infection and death due to COVID-19. In Iran, the vaccination program officially started on February 9, 2021, with the priority for health care providers [13].

The vaccination program has faced challenges despite significant progress in controlling the COVID-19 pandemic [14]. One of these challenges is people's opposition to the COVID-19 vaccine injection. In some studies, some reasons for opposition to vaccination have been reported, such as fear of short-term and long-term side effects of the vaccine, ineffectiveness of the vaccine and re-infection of the COVID-19 disease, mistrust of the vaccine production process, and cultural and religious reasons [1, 15, 16]. In previous studies, the most common side effects were fever, injection site pain, fatigue, headache, nausea and vomiting, and joint pain [17-20].

In the review of the literature, most of the studies were conducted on the immunogenicity of different types of vaccines and also in the form of clinical trials with the aim of the effectiveness of the vaccines [11, 21]. Meanwhile, investigating the side effects of the vaccine as well as re-infection of the COVID-19 disease after the vaccine has been given less attention as one of the reasons for not accepting the COVID-19 vaccine [22]. On the other hand, since the crises similar to the COVID-19 pandemic may challenge the human society again in the future, it is important to examine the strengths and weaknesses of the determined strategies.

OBJECTIVES:

The main objectives of this study were to determine the rate of COVID-19 re-infection after coronavirus vaccination and to identify the type and frequency of vaccine-related side effects among the employees of the University of Social Welfare and Rehabilitation Sciences in Tehran, Iran. Accordingly, this study specifically addresses the following research questions: (1) What side effects are experienced after COVID-19 vaccination among university employees? (2) What is the rate of COVID-19 re-infection following different doses of vaccination?

METHODS

STUDY DESIGN AND PARTICIPANTS

This cross-sectional descriptive study was conducted from December 2021 to March 2022 in Tehran. The research population included all employees of the University of Social Welfare and Rehabilitation Sciences. This university was established as one of the universities affiliated with the Ministry of Health of Iran in 1992 in the northern region of Tehran, the capital of Iran. This university is known as the hub of rehabilitation sciences in the country and has 22 educational departments, eight research centers, two specialized hospitals, and affiliated medical centers.

All university employees in administrative, therapeutic, and educational environments who met the inclusion criteria completed the questionnaire. Inclusion criteria were injection of the first and second dose of one of the Sputnik V, AstraZeneca, Sinopharm, Bharat, and Barekat (vaccine produced in Iran) vaccines, not having an acute disease with symptoms similar to COVID-19 or influenza.

From the community of two thousand university employees, 351 people were selected using the ratio formula and considering $P=50\%$ as the sample size. Based on the list received from the university's vice-chancellor for treatment, the names of all individuals who had received the coronavirus vaccine were sampled using a table of random numbers and simple random sampling, yielding a 100% response rate.

DATA COLLECTION INSTRUMENTS

A researcher-made questionnaire was used to collect data. The designed questionnaire has three main components, including 1) demographic characteristics (questions such as age, gender, education etc), 2) questions related to complications after vaccine injection (both mild/common side effects; such as fever, headache, injection site pain, fatigue, nausea and less common/severe symptoms; such as limb paralysis, bleeding, loss of consciousness), and 3) questions related to re-infection with COVID-19 disease after vaccine injection (addressing history of infection after vaccination, timing, number of episodes, and severity). For the validity of the questionnaire, the content validity method was used. In this way, the designed questionnaire was given to 10 faculty members and experts in the field of health, and their opinions about the questions were collected. Next, the CVR and CVI indexes were also calculated (CVI=0.82, CVR=0.88). Experts' opinions were raised in the meeting of the research team members, and finally, the necessary corrections were made, and the final version of the questionnaire was determined for data collection. In order to verify the reliability of the designed questionnaire, the test-retest method and the correlation coefficient were used. Based on this, the questionnaire was distributed among 20 participants and completed by them. After 14 days, the questionnaire was given to the same people again. Finally, after calculating the Pearson correlation coefficient ($r=0.83$), the reliability of the designed tool was confirmed.

PROCEDURE

After obtaining the necessary permits, the researchers went to the research environment. After explaining the study's objectives and ensuring the confidentiality of participants' information, the questionnaires were distributed to the sample population. After completing the questionnaires, they were reviewed, and incomplete items were removed.

ETHICAL CONSIDERATIONS

The study was approved by the ethics committee affiliated with the University of Social Welfare and Rehabilitation Sciences on 09/03/2022 (approval number "IR.USWR.REC.1400.316"). The participants signed an informed consent form before their participation. They were assured of the confidentiality of their data.

DATA ANALYSIS

The collected data were analyzed with IBM's SPSS (version 23) software. To describe and categorize data from descriptive statistics (frequency distribution, mean, and standard deviation) and for the relationship between demographic variables and the rate of re-infection with COVID-19, chi-square and t-tests, and Pearson's correlation coefficient at a significant level of $p<0.05$ were used.

RESULTS

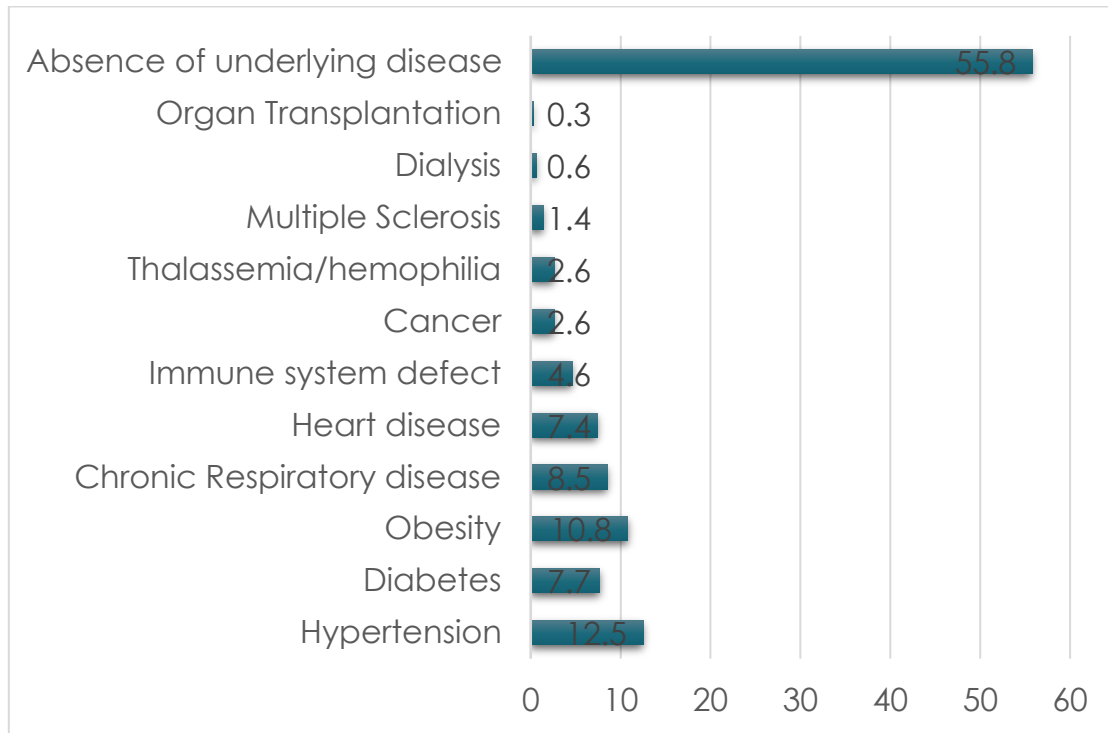
BACKGROUND CHARACTERISTIC

The data included 351 people, 43% of whom were men, with an average age of 39.9 ± 9.9 years. More than 70% were married, and the majority had a bachelor's degree. Approximately 64% of the participants were working at Razi Hospital, and more than 62% reported encountering a COVID-19 patient (Table 1). More than 55% of the participants did not have any underlying disease, and the most common underlying disease was hypertension. Obesity and chronic respiratory disease had the next highest prevalence rates (Figure 1). The relationship between each of these diseases and contracting COVID-19 after vaccination was not significant for any of them (p -value > 0.05).

TABLE 1: SOCIO-DEMOGRAPHIC CHARACTERISTICS OF THE RESPONDENTS

Variable	Label	N (%)
Gender	Female	200(57)
	Male	151(43)
Marriage status	Married	247(70.37%)
	Single	91(25.9)
	Divorced	5(1.4)
	Widow	2(0.6)
Education	Elementary	8(2.3)
	Diploma	55(15.7)
	Bachelor	147(41.9)
	Master	99(28.2)
	Doctorate	7(2)
	Ph.D.	33(9.4)
Place of activity	Campus of the university	58(16.5)
	Razi Hospital	226(64.4)
	Rofaydeh Hospital	31(8.8)
	Asma rehabilitation center	16(4.6)
	Nezam mafi clinic	20(5.7)
Exposure to the COVID-19 patient	Yes	220(62.7)
	No	128(36.5)
Name of Vaccine	Sputnik V	129(36.8)
	Oxford AstraZeneca	131(37.3)
	Sinopharm	71(20.2)
	Baharat	11(3.1)
	Barekat (Iranian vaccine)	9(2.6)

FIGURE 1: DISTRIBUTION OF UNDERLYING HEALTH CONDITION (PERCENTAGES %)



SIDE EFFECTS OF COVID-19 VACCINES

About 76% (CI: 71.3–80.4%) of the participants experienced side effects after receiving the first dose of the vaccine, and the most common side effects were fever and sweating, followed by weakness, headache, and pain at the injection site. After receiving the second and booster doses of the vaccine, nearly 75% (CI: 69.2–78.6%) and 77% (CI: 72.5–81.5%) of participants, respectively, reported vaccine side effects. Less than 1% of the samples, after receiving the second dose of the vaccine, experienced limb paralysis, and more than 42% reported fever and sweating as the most common complications experienced. As with the first and second doses, the most common side effects after receiving the booster dose were fever and sweating, and weakness and chills were the next most common. Limb paralysis, blurred vision and bleeding were the least reported side effects after receiving the booster dose. Figure 2 and Table 2 illustrate the distribution of side effects associated with COVID-19 vaccines.

FIGURE 2: DISTRIBUTION OF SIDE EFFECTS OF COVID-19 VACCINES (PERCENTAGE)

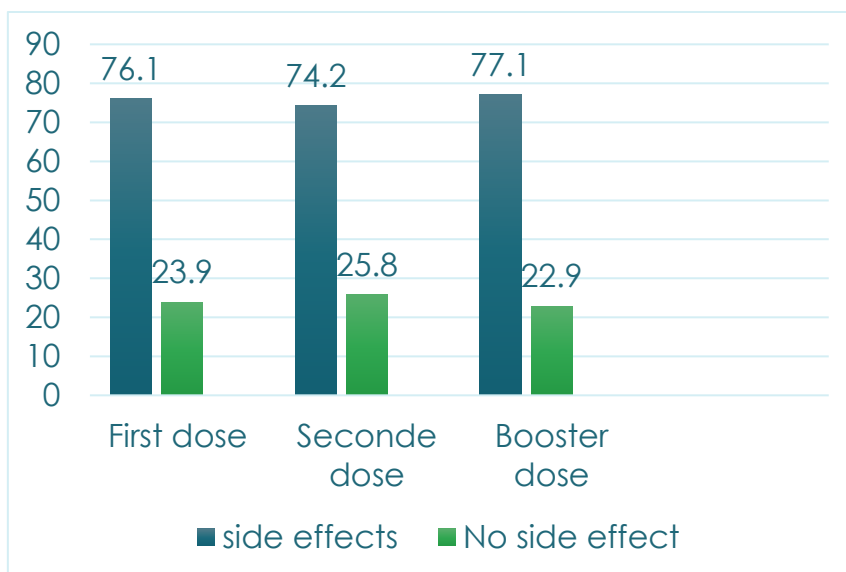


TABLE 2: DISTRIBUTION OF SIDE EFFECT OF COVID-19 VACCINES.

Side effect	N	First dose %(CI)	N	Second dose %(CI)	N	Third dose %(CI)
Fever and sweating	149	42.5 (37.2 - 47.8)	149	42.5 (37.2 - 47.8)	82	23.4 (19.0 - 28.1)
weakness	134	38.2 (33.1 - 43.5)	134	38.2 (33.1 - 43.5)	80	22.8 (18.5 - 27.5)
Headache	118	33.6 (28.7 - 38.8)	118	33.6 (28.7 - 38.8)	56	16.0 (12.3 - 20.2)
Injection site pain	115	32.8 (27.9 - 37.9)	83	23.6 (19.3 - 28.4)	55	15.7 (12.0 - 19.9)
Shivering	98	27.9 (23.3 - 32.9)	98	27.9 (23.3 - 32.9)	66	18.8 (14.9 - 23.3)
Body pain	62	17.7 (13.8 - 22.1)	62	17.7 (13.8 - 22.1)	24	6.8 (4.4 - 10.0)
Nausea	35	10.0 (7.0 - 13.6)	35	10.0 (7.0 - 13.6)	26	7.4 (4.9 - 10.7)
Body numbness	33	9.4 (6.6 - 12.9)	33	9.4 (6.6 - 12.9)	15	4.3 (2.4 - 7.0)
Chest pain	29	8.3 (5.6 - 11.7)	29	8.3 (5.6 - 11.7)	8	2.3 (1.0 - 4.4)
Shortness of breath	26	7.4 (4.9 - 10.7)	26	7.4 (4.9 - 10.7)	24	6.8 (4.4 - 10.0)
Skin lesions	17	4.8 (2.8 - 7.6)	17	4.8 (2.8 - 7.6)	10	2.8 (1.4 - 5.2)
Blurred vision	11	3.1 (1.6 - 5.5)	11	3.1 (1.6 - 5.5)	3	0.9 (0.2 - 2.5)
Diarrhea	10	2.8 (1.4 - 5.2)	10	2.8 (1.4 - 5.2)	5	1.4 (0.5 - 3.3)
Bleeding	6	1.7 (0.6 - 3.7)	6	1.7 (0.6 - 3.7)	4	1.1 (0.3 - 2.9)
loss of consciousness	4	1.1 (0.3 - 2.9)	4	1.1 (0.3 - 2.9)	0	0.0 (0.0 - 0.0)
Paralysis	3	0.9 (0.2 - 2.5)	3	0.9 (0.2 - 2.5)	2	0.6 (0.1 - 2.0)

Rare events (paralysis, bleeding, loss of consciousness) were self-reported and not clinically confirmed.

RE-INFECTION AFTER VACCINATION COVID-19

About 42% of the participants were infected with COVID-19 disease before the vaccine injection, and the statistics of COVID-19 infection after receiving the 1st, 2nd and 3rd doses were 16%, 19.1% and 14.8%, respectively (Table 3). Survival analysis was used to estimate the probability of the occurrence of COVID-19 in each of the time intervals obtained from the interval between the injection of the vaccine and the occurrence of COVID-19. Also, the probability of occurrence was calculated and reported separately for vaccines injected in doses up to the third dose. The probability of cumulative incidence of COVID-19 after the first dose of vaccine (independent of the type of vaccine) has been shown in the studied sample. Based on this, the probability of cumulative occurrence of COVID-19 in the first 10 days after the injection of the first, second and booster doses of the vaccine is equal to 38%, 18% and 15%, respectively. Figure 3-5 show the time of infection with COVID-19 (days) after injection of doses of vaccine.

TABLE3: FREQUENCY DISTRIBUTION OF COVID-19 INFECTION IN PARTICIPANTS

COVID-19 infection	Before injection of vaccine N (%)	After injection/first dose N (%)	After injection/second dose N (%)	After injection/booster dose N (%)
Yes	151 (43)	56 (16)	67 (19.1)	52 (14.8)
No	200 (57)	294 (84)	282 (80.9)	299 (85.2)

FIGURE 3: TIME OF INFECTION WITH COVID- 19 (DAYS)/FIRST DOSE

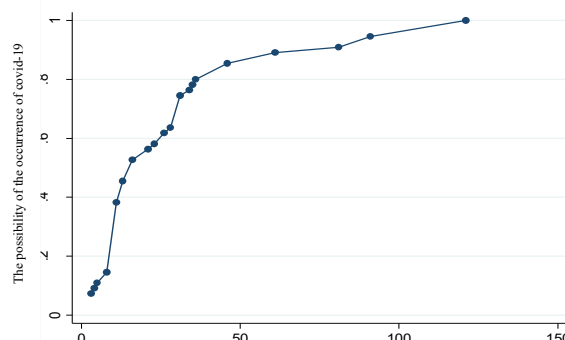


FIGURE 4: TIME OF INFECTION WITH COVID-19 (DAYS)/SECOND DOSE

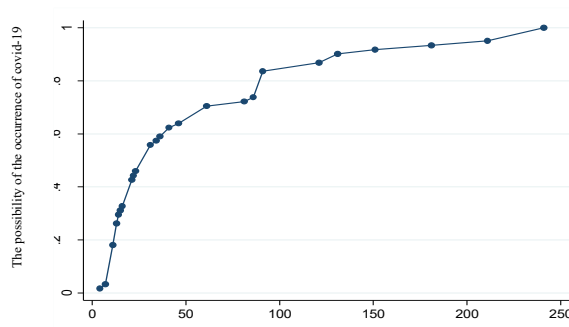
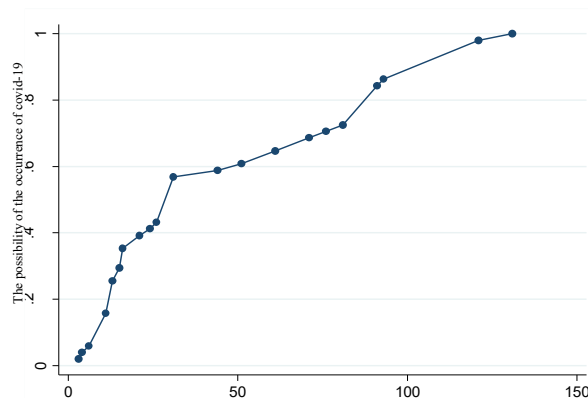


FIGURE 5: TIME OF INFECTION WITH COVID-19 (DAYS)/BOOSTER DOSE



DISCUSSION

This study was conducted with the aim of determining the rate of re-infection with COVID-19 after coronavirus vaccination and the side effects of vaccination among the employees of the University of Social Welfare and rehabilitation Sciences in 2022. In line with the general aim of the study, the findings showed that 42.7% of the samples had a history of COVID-19 disease before injecting the coronavirus vaccine. In the following, 16%, 19.1%, and 14.8% of the samples were infected with COVID-19 after the first dose, second dose, and third dose of the vaccine, respectively.

In addition, in the analysis carried out, the survival analysis of the probability of cumulative occurrence of COVID-19 after the first dose of vaccine (independent of the type of vaccine) in the studied sample showed that the probability of cumulative occurrence of COVID-19 in the first 10 days after the injection of the vaccine has it is important (38%). This finding shows that the first dose of the vaccine, regardless of its type, cannot have an acceptable immunity in preventing the infection of COVID-19. On the other hand, the cumulative probability of getting infected with COVID-19 after the second dose of the vaccine within 10 days after injecting the second dose of the vaccine, regardless of its type, should be significantly reduced (infection rate 18%). Also, this probability is within 10 days after the injection. The booster dose (the third dose) also decreases further (15%). In explaining the above findings, it can be stated that the completion of the COVID-19 vaccination, regardless of the type of vaccine, has been able to reduce the rate of infection or re-infection with COVID-19 in the population covered by the vaccination.

However, the cumulative probability of contracting COVID-19 within 10 days after the injection of different types of vaccines in the first dose is different from each other, so this probability is higher for the Sinopharm vaccine compared to other vaccines and lower for the AstraZeneca vaccine. On the other hand, the cumulative probability of getting infected with COVID-19 within 10 days after the injection of the second dose and booster vaccine is not much different among

different types of vaccine. Based on this, it is not possible to conclude which of the types of vaccines are more effective and immunogenic compared to other types of COVID-19 vaccines, but it can be concluded that completing the course of COVID-19 vaccination can significantly reduce the risk of contracting COVID-19. Babamahmoudi et al. (2021) have stated that in 90% of health service providers who injected both doses of the Sputnik vaccine, a high level of immunogenicity was observed in the immunometric tests of these people [13]. Menni et al. (2022) also reported that people have the highest level of immunogenicity in the prevention of COVID-19 within 5 months after the injection of the main doses of Pfizer, AstraZeneca, and Moderna vaccines [23].

The findings of the study showed that 24% of the samples did not report any side effect after the injection, but the other samples experienced various types of side effects following the injection of the vaccine. "Fever and sweating" was the most common side effect reported after the injection of the first, second, and booster doses. Also, the side effects of "weakness", "headache" and "injection site pain" were the most common side effects in the first dose of corona vaccine. In addition, "shivering", "headache", "weakness", "chilling" and "injection site pain" were the most common side effects reported in the second dose of the vaccine. Finally, in the third dose of corona vaccine, the side effects of "weakness", "shivering" and "injection site pain" were reported as the most common side effects. Compared to other studies that have investigated the side effects of coronavirus vaccines, similar results are seen. Babamahmoudi et al. (2021) reported the most common side effects after the injection of the coronavirus vaccine in the order of pain at the injection site, weakness, body pain, headache, and fever [13]. Aznab et al. (2023) also investigated the side effects of the coronavirus vaccine in cancer patients, and the most common side effects were fever, injection site pain, dizziness, body pain, and headache, respectively [24]. Yasmin et al. (2022) also reported in their study among young Pakistanis, that the most common side effects of various corona vaccines, including Sinovac, Sinopharm, and Moderna, were pain at the injection site, muscle weakness, headache, fever, and fatigue, respectively [25]. Duva et al. (2023) in determining the complications after the corona-vaccine injection in Ethiopia, reported the most common complications after the corona-vaccine injection in the order of fever, headache, fatigue and weakness, injection site pain, and nausea [18].

In explaining the findings from the analysis of the side effects reported after the vaccine doses, it seems that the main side effects reported were general symptoms and the body's response to the coronavirus injection, which is the case for many other common disease vaccines. But the remarkable thing about the reported side effects is that the frequency of common side effects reported in the third dose has decreased compared to the first and second doses.

In the implementation of any study, there are some limitations that should be considered. In this study, the main limitation was the self-completion of the questionnaire and self-reporting of side effects, which may introduce recall or reporting bias. Additionally, the study was conducted on a sample of 351 employees using available random sampling, which may limit the generalizability of the findings to the broader population. The sample size and specific characteristics of the participants might not fully represent all demographic or occupational groups, and therefore, the results should be interpreted with caution.

CONCLUSION

The results of this study, like those of other research conducted on the COVID-19 vaccine, indicate that the vaccine is safe and can reduce the risk of contracting COVID-19. Additionally, receiving both doses of the vaccine will induce immunity, and receiving only one dose alone will not reduce the risk of infection. Also, the most common side effects reported after injection were "fever and sweating", "body weakness", "headache", and "injection site pain".

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