




# Pediatric and adolescent COVID-19 vaccination side effects: A retrospective cohort study of the Iranian teenage group in 2021

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## Abstract

To determine the safety and efficacy profile of teenager COVID-19 vaccination. In this retrospective cohort study, contact numbers of parents of teenagers under 18 years of age referred to a teenager vaccination centers in Tehran-Iran to receive the corona vaccine were collected, and the following information was obtained via the phones: demographic information, type of vaccine, and the number of doses received, as well as additional information like complications and required treatments. Eleven thousand forty-two subjects aged 10–18 years, mean age  $14.55 \pm 1.83$  year including 5374 boys and 5768 girls were investigated. 88.1% received the Sinopharm and 11.9% the Soberana vaccine. General side effects, including fatigue, fever and chills, injection site pain and dizziness, and so forth happened in 2978 cases; 7421 children presented with at least one general or organ-specific side effect following vaccination, including potentially critical side effects, such as vascular injuries, respiratory complication, and so forth. 0.1% of the subject needed hospital admission. The breakthrough infection happened in 200 individuals. Our study shows that Sinopharm and Soberana (PastoCoVac) COVID-19 vaccines are generally safe with no serious side effects in less than 18 years old.

COVID-19 infection and reinfection can occur after vaccination, but the incidence is actually tolerable and significantly lower than in the unvaccinated group.

**KEYWORDS**

adolescent, children, COVID-19, efficacy, pediatric, safety, vaccination

## 1 | INTRODUCTION

COVID-19 pandemic is now the most important health issue worldwide. On February 19, 2020, the first case of COVID-19 was announced in Iran, and COVID-19 development was reported in 8.5 million cases since the beginning of pandemic about 125000 deaths.<sup>1</sup> Although COVID-19 is transmitted rapidly via the respiratory tract, it can affect other organs in the body. COVID-19 is characterized by symptoms, such as fever, dry cough, and fatigue that can involve both the respiratory system<sup>2,3</sup> and nonrespiratory organs with different manifestations, including the kidneys liver, heart, eye, and skin.<sup>1-10</sup> COVID-19 pandemic has already placed a heavy physical and psychological burden on society. To date, over 180 million people worldwide were infected with COVID-19, of which approximately 5.4 million have died.<sup>11</sup> Although measures such as social distancing and using masks were important to prevent the further spread of COVID-19, they come with huge economic, social, and educational costs. Even though most deaths occur in the elderly, significant complications and deaths have been reported in children too.<sup>12</sup> Children of all ages are susceptible to COVID-19 with varying manifestations of the disease.<sup>13</sup> Although the majority of COVID-19 cases are asymptomatic or mild in children, 10.6 out of 100 000 children aged 5–17 years need to be admitted to the intensive care unit.<sup>14-16</sup> In addition to the direct benefits of active immunity against COVID-19, safe and effective vaccination of children can dramatically reduce the significant social impact of the disease on children. Vaccines are an important breakthrough in the fight against the COVID-19 pandemic, which is one of the most important tools to prevent and control the disease today. Extraordinary efforts were made to rapidly develop the COVID-19 vaccine to protect vulnerable individuals from severe infections, thereby limiting the adverse effects of the disease on social health and socioeconomic aspects. Hence, the need for medical, social, and economic response to the COVID-19 epidemic led to the rapid development and production of a large number of vaccines. Recent studies have all documented the immunogenicity of the vaccine in adults and the elderly, and only a handful of studies have examined the efficacy of these vaccines in children.<sup>17,18</sup> Therefore, one of the most controversial issues regarding the use of these vaccines is the vaccination of people under 18 years of age. Clinical trials and studies have been more focused on the adult age group.<sup>19-22</sup> The benefits and safety of pediatric vaccination are still unclear and few studies were conducted in this area. Therefore, the question arises whether vaccination should be given to children or not and whether these vaccines are safe enough for them. As children play an important

role in the transmission of the disease, COVID-19 vaccines should show their complete safety and efficacy in addition to preventing further transmission of disease, as well as preventing the complications of childhood vaccination and possible side effects of COVID-19 vaccine in children. Regarding the start of vaccination of people under 18 years in Iran, we examined the safety and possible side effects of vaccination under 18 years to provide a safe and effective vaccine to reduce the psychological burden of this disease on families and the community, protect children from severe illness, and thus, limit the negative effects of the disease on health and the socioeconomic dimensions of the community. This study is one of the national studies with a large sample size aimed to evaluate the safety and efficacy (regarding the breakthrough infection) of COVID-19 vaccination in Iranian children and adolescents.

## 2 | MATERIALS AND METHODS

The study population included all children (census method) who were referred to one of the designated vaccination centers for people less than 18 years of age and received the most common COVID-19 vaccine in children, including Soberana (PastoCoVac) and Sinopharm since the beginning of the vaccination of children against COVID-19 in 2021. At the beginning of the project and thanks to the coordination with the processing assistant of the COVID-19 committee of the province of Tehran, one of the most populous centers was selected. The basic information about the people, including gender, age, education, type of vaccine, and telephone number of the people are obtained via the treatment deputy of the Iran University of Medical Science. Then, by calling the parents of the individuals, additional information, including the history of underlying diseases, the history of COVID-19 in themselves and children, the time of vaccination (first and second doses) in parents, and in vaccinated children, as well as side effects. The necessary information is collected via a predetermined checklist by trained interviewers through the phone.

### 2.1 | Statistical issue

The data were analyzed by SPSS version 20. Descriptive statistics for variables were expressed in terms of their type, frequency, percentage, mean, and standard deviation. To compare quantitative variables, an independent *t*-test and to compare the frequency of

outcomes, the  $\chi^2$  test was used. Moreover,  $p$  value less than 0.05 was considered significant.

### 3 | RESULTS

In this study, 11 042 subjects aged 10–18 years were investigated, including 5374 boys (47.8%) and 5768 girls (52.2%). Moreover, 88.1% of the children ( $N = 9727$ ) were vaccinated by Sinopharm and 11.9% ( $N = 1315$ ) by Soberana (PastoCoVac). Regarding vaccine dose, 80.5% ( $N = 8890$ ) received their second dose (Table 1).

Regarding the ABO group, +A and then +O were the dominant blood group (Figure 1).

In general, 200 children developed COVID-19 after vaccination in which their dominant blood group was +A ( $N = 54$ ) following +O ( $N = 25$ ) ( $p = 0.04$ ) (Table 2).

All subjects who developed COVID-19 after vaccination had a previous history of infection with COVID-19, and there was no difference regarding re-development of COVID-19 between the two groups of Sinopharm (1.9%) and Soberana (1.5%) ( $p = 0.400$ ). After receiving both doses, the increase risk to develop COVID-19 was the lowest ( $p < 0.001$ ) (Table 3).

Regarding general side effects, their generality after vaccination can be seen in Table 4. Fatigue, pain, and dizziness were higher in the Sinopharm group compared to the Soberana group ( $p < 0.05$ ), and a

total of 3289 children developed general side effects following vaccination (0.2978 i.e., 2978 cases per 10 000 vaccinated children or about 30% [exactly 29.78%] of vaccinated children) (Table 5).

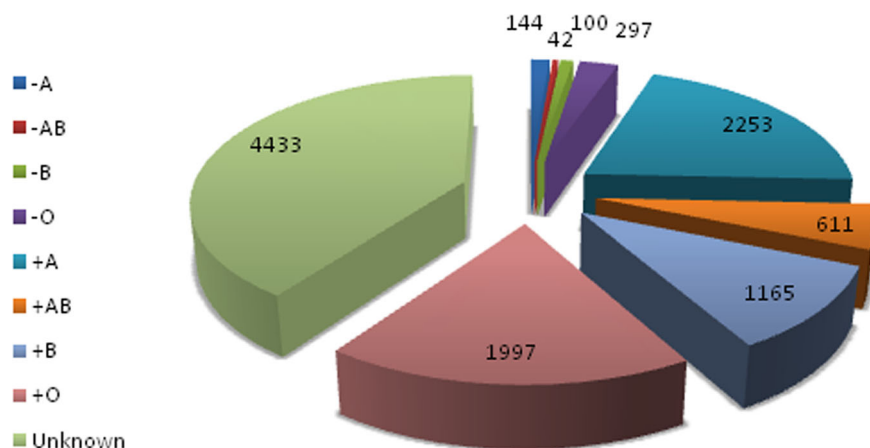
Regarding specific side effects, 7421 (67%) children experienced at least one general or organ-specific side effect, that is, dermatological, gastrointestinal, respiratory, articular, neurological, cardiovascular, and renal, as shown in Table 6. In this table, we present the items mentioned in our checklist in detail and the other organ-specific side effects, which we considered minor complaints, similar to Table 4.

Regarding critical side effects, myocardial infarction, angioedema, ataxia, and arthritis were higher in the Soberana group compared to the Sinopharm group ( $p < 0.05$ ). Totally, 421 children developed major side effects (observed in 3.73% of all population and account for 5.5% of all observed side effects) (Table 7).

The start and finish time of side effects after developing COVID-19 in the patients who got vaccination is of great importance. General side effects following the COVID-19 vaccination were assessed regarding start and finish time and showed that the two vaccines of Soberana and Sinopharm are significantly different ( $p < 0.001$ ). For example, 31.8% of the participants receiving Soberana experienced general side effects exactly the same day of vaccination, while in the Sinopharm group it was 25.1%. Soberana shows early side effects compared to Sinopharm. Moreover, 7.2% of the participants receiving Soberana experienced general side effects 3 days after the injection, but it was 5.7% in the Sinopharm group.

**TABLE 1** Quantitative demographic characteristics of the subjects

Variable	Value
Age (year) mean $\pm$ SD, min, max.	14.55 $\pm$ 1.830, 10, 18
Weight, mean $\pm$ SD, min, max	57.05 $\pm$ 15.614, 8, 176
Height, mean $\pm$ SD, min, max (centimeter)	162.62 $\pm$ 14.497, 100, 198
Covid-19 history duration, mean $\pm$ SD, min, max	11.88 $\pm$ 8.789, 1, 90
Cardiovascular disease, $N$ (%)	67, (0.6)
Renal disease, $N$ (%)	36, (0.3)
Respiratory disease, $N$ (%)	148, (1.3)
Immunodeficiency, $N$ (%)	53, (0.5)
Cancer, $N$ (%)	15, (0.1)
Undergoing radiotherapy, $N$ (%)	13, (0.1)
Undergoing chemotherapy, $N$ (%)	15, (0.1)
Undergoing corticosteroid therapy, $N$ (%)	23, (0.2)
Vaccine first dose, $N$ (%)	2152, (19.5)
Vaccine second dose, $N$ (%)	8890, (80.5)
Sinopharm vaccine, $N$ (%)	9727, (88.1)
Soberana (PastoCoVac) vaccine, $N$ (%)	1315, (11.9)
Need to admission, $N$ (%)	15, (0.1)
Outpatients treated by Remdesivir, $N$ (%)	30, (0.3)
No need for admission, $N$ (%)	143, (1.3)



**FIGURE 1** Frequency of ABO group among studied subjects

**TABLE 2** Frequency of ABO group among studied subjects across subjects developed Covid-19 after vaccination

Covid-19 after vaccination		Blood type									Total	$\chi^2$ p value
		-A	-AB	-B	-O	+A	+AB	+B	+O	Unknown		
Yes	N	3	3	1	5	54	19	21	25	69	200	22.437, 0.04
	%	2.1	7.1	1.0	1.7	2.4	3.1	1.8	1.3	1.6	1.8	
No	N	141	39	99	292	2199	592	1144	1972	4364	10842	
	%	97.9	92.9	99.0	98.3	97.6	96.9	98.2	98.7	98.4	98.2	

**TABLE 3** Frequency of subjects who developed Covid-19 after vaccination across vaccine types and COVID-19 history

Covid-19 after vaccination		Vaccine type			COVID-19 history			Vaccine dose		
		Soberana	Sinopharm	$\chi^2$ p value	Yes	No	$\chi^2$ p value	First	Second	$\chi^2$ p value
Yes	N	20	180	0.708, 0.400	200	0	595.01, <0.001	124	66	10311.9, <0.001
	%	1.5	1.9		7.1	0.0		100.0	100.0	
No	N	1295	9547		2616	8226		0	0	
	%	98.5	98.1		92.9	100.0		0.0	0.0	

Also, the percent reported for the day after injection was 14.6% and 11.3% for Soberana and Sinopharm, respectively, while the Sinopharm had higher value in "three weeks after the injection" and "two weeks after injection,"s (Table 8). The length of general side effects was short in Soberana compared to Sinopharm in which side effects finished for Soberana versus Sinopharm as follows: "The same day of the injection" (10.8% vs. 7.9%), "The day after the injection" (14.2 vs. 13.3), "During three days after the injection" (19.7% vs. 13.9%).

## 4 | DISCUSSION

It seems that comprehensive vaccination is the most cost-effective approach to control the COVID-19 pandemic; however, medications for treating COVID-19 are needed as well, while the focusing on the vaccine in studies can be helpful in preventing mortality and morbidity.<sup>21-27</sup> Like other medicines, the corona

vaccine has side effects. One of the main reasons some people choose not to be vaccinated is the fear of these side effects.<sup>28</sup> Most of these complications are very mild and transient, but vaccination is so large that rare but more serious complications need to be considered.<sup>28</sup> Most studies have focused on adults population regarding both the early stages of vaccine development and the follow-up stages of vaccine complications. The need for corona vaccination in children is obvious to all and is not the subject of this article. Several COVID-19 vaccines were developed but Soberana (PastoCoVac) and Sinopharm were approved for under 18 years in Iran. This study aimed to evaluate the safety and side effects of vaccination against COVID-19 in children <18 years. In this retrospective cohort study, which was performed by telephone, 11042 people under 18 years of age were studied. Two thousand one hundred fifty-two of them only one dose, and 8890 cases received two doses of vaccine. 88.1% of people received the Sinopharm vaccine, and 11.9% received the Soberana vaccine. Side effects following vaccination were divided into two

**TABLE 4** Generality of side effects after vaccination

Variable	Frequency	Percent in all targeted populations (11 042)
Any side effect	7421	67.20
General side effects	3289	29.78
Noncritical organ-specific side effects	4132	37.42
Organ-specific major (potentially critical) side effects	412	3.73 & 5.5% of all side effects
Dermatological side effects	155	0.0140
Gastrointestinal side effects	267	0.0241
Respiratory side effects	460	0.0416
Joint-related side effects	107	0.0096
Neurological side effects	258	0.0233
Cardiovascular and hematological side effects	55	0.0049
Renal side effects	8	0.0007
Organ-specific side effects other than our checklist items	2822	25.55

**TABLE 5** General side effects following vaccination

General side effects	Vaccine type		Total	$\chi^2$ p value
	Soberana	Sinopharm		
Allergy to vaccine				
Frequency	14	107	121	1.208, 0.547
Percent (%)	1.1	1.1	1.1	
General weakness				
Frequency	136	1039	1175	1.527, 0.466
Percent (%)	10.3	10.7	10.6	
Fever				
Frequency	107	809	916	0.49, 0.824
Percent (%)	8.1	8.3	8.3	
Shiver (chills)				
Frequency	32	273	305	0.601, 0.438
Percent (%)	2.4	2.8	2.8	
Fatigue				
Frequency	173	1786	1959	21.508, <0.001
Percent (%)	13.2	18.4	17.7	
Dizziness				
Frequency	64	643	707	5.876, 0.015
Percent (%)	4.9	6.6	6.4	
Pain				
Frequency	97	985	1082	9.912, 0.002
Percent (%)	7.4	10.1	9.8	

**TABLE 6** Rate of organ-specific side effects following COVID-19 vaccination

Dermatological side effects following vaccination	
Edema	
Frequency	12
Percent	0.1%
Angioedema	
Frequency	6
Percent	0.1%
Redness	
Frequency	22
Percent	0.2%
Wheal	
Frequency	11
Percent	0.1%
Itching	
Frequency	38
Percent	0.3%
Rash	
Frequency	29
Percent	0.3%
Tenderness	
Frequency	4
Percent	0.0%
Bruise	
Frequency	11
Percent	0.1%
Abscess	
Frequency	10
Percent	0.1%
Hematoma	
Frequency	5
Percent	0.0%
Eczema	
Frequency	7
Percent	0.1%
Gastrointestinal side effects following vaccination	
Nausea	
Frequency	50
Percent	0.5%
Vomiting	
Frequency	23

(Continues)

TABLE 6 (Continued)

Dermatological side effects following vaccination	
Percent	0.2%
Diarrhea	
Frequency	38
Percent	0.3%
Constipation	
Frequency	24
Percent	0.2%
Abdominal pain	
Frequency	55
Percent	0.5%
Dyspepsia	
Frequency	14
Percent	0.1%
Appetite loss	
Frequency	55
Percent	0.5%
GI bleeding	
Frequency	8
Percent	0.1%
Respiratory side effects following vaccination	
Dyspnea	
Frequency	54
Percent	0.5%
Chest pain	
Frequency	59
Percent	0.5%
Palpitation	
Frequency	49
Percent	0.4%
Cough	
Frequency	52
Percent	0.5%
Sputum	
Frequency	27
Percent	0.2%
Sore throat	
Frequency	52
Percent	0.5%
Rhinorrhea	
Frequency	52
Percent	0.5%

TABLE 6 (Continued)

Dermatological side effects following vaccination	
Nose congestion	
Frequency	51
Percent	0.5%
Nose itching	
Frequency	22
Percent	0.2%
Throat itching	
Frequency	31
Percent	0.3%
Face itching	
Frequency	11
Percent	0.1%
Joint-related side effects following vaccination	
Arthritis	
Frequency	3
Percent	0.0%
Arthralgia	
Frequency	34
Percent	0.3%
Joint swelling and redness	
Frequency	6
Percent	0.1%
Muscle pain	
Frequency	63
Percent	0.6%
Neurological side effects following vaccination	
Paresthesia	
Frequency	18
Percent	0.2%
Convulsion	
Frequency	5
Percent	0.0%
Blur vision	
Frequency	33
Percent	0.3%
Headache	
Frequency	101
Percent	0.9%
Vertigo	
Frequency	57
Percent	0.5%

TABLE 6 (Continued)

Dermatological side effects following vaccination	
Insomnia	
Frequency	37
Percent	0.3%
Ataxia	
Frequency	7
Percent	0.1%
Cardiovascular and hematological side effects following vaccination	
Arrhythmia	
Frequency	18
Percent	0.2%
Thrombosis	
Frequency	4
Percent	0.0%
Pericarditis	
Frequency	3
Percent	0.0%
Myocardial infarction	
Frequency	3
Percent	0.0%
Anemia	
Frequency	17
Percent	0.2%
Thrombocytopenia	
Frequency	3
Percent	0.0%
Leukocytosis	
Frequency	5
Percent	0.0%
Leukopenia	
Frequency	2
Percent	0.0%
Renal side effects following vaccination	
Proteinuria	
Frequency	4
Percent	0.0%
Hematuria	
Frequency	2
Percent	0.0%
Renal dysfunction	
Frequency	2
Percent	0.0%

TABLE 7 Major side effects following vaccination

Potentially critical side effects	Vaccine type		Total	$\chi^2$ p value
	Soberana	Sinopharm		
Angioedema				
Frequency	3	3	6	8.303, 0.004
Percent (%)	0.2	0.0	0.1	
Skin bruise				
Frequency	3	8	11	1.908, 0.167
Percent (%)	0.2	0.1	0.1	
Skin hematoma				
Frequency	2	3	5	2.544, 0.111
Percent (%)	0.2	0.0	0.0	
Abdominal pain				
Frequency	8	47	55	0.366, 0.545
Percent (%)	0.6	0.5	0.5	
GI bleeding				
Frequency	2	6	8	1.308, 0.253
Percent (%)	0.2	0.1	0.1	
Dyspnea				
Frequency	6	48	54	0.033, 0.856
Percent (%)	0.5	0.5	0.5	
Chest pain				
Frequency	9	50	59	0.633, 0.426
Percent (%)	0.7	0.5	0.5	
Palpitation				
Frequency	7	42	49	0.265, 0.607
Percent (%)	0.5	0.4	0.4	
Arthritis				
Frequency	2	1	3	4.948, 0.026
Percent (%)	0.2	0.0	0.0	
Joint swelling and redness				
Frequency	3	3	6	5.215, 0.22
Percent (%)	0.2	0.0	0.1	
Paresthesia				
Frequency	2	16	18	0.011, 916
Percent (%)	0.2	0.2	0.2	
Convulsion				
Frequency	1	4	5	0.312, 0.576
Percent (%)	0.1	0.0	0.0	
Blur vision				
Frequency	5	28	33	0.332, 0.565
Percent (%)	0.4	0.3	0.3	

(Continues)

TABLE 7 (Continued)

Potentially critical side effects	Vaccine type		Total	$\chi^2$ , <i>p</i> value
	Soberana	Sinopharm		
<b>Vertigo</b>				
Frequency	6	51	57	0.104, 0.747
Percent (%)	0.5	0.5	0.5	
<b>Ataxia</b>				
Frequency	3	4	7	4.225, 0.040
Percent (%)	0.2	0.0	0.1	
<b>Proteinuria</b>				
Frequency	1	3	4	0.518, 0.472
Percent (%)	0.1	0.0	0.0	
<b>Hematuria</b>				
Frequency	1	1	2	1.737, 0.187
Percent (%)	0.1	0.0	0.0	
<b>Renal dysfunction</b>				
Frequency	1	1	2	1.737, 0.187
Percent (%)	0.1	0.0	0.0	
<b>Arrhythmia</b>				
Frequency	4	14	18	1.507, 0.220
Percent (%)	0.3	0.1	0.2	
<b>Thrombosis</b>				
Frequency	2	2	4	3.476, 0.062
Percent (%)	0.2	0.0	0.0	
<b>Pericarditis</b>				
Frequency	1	2	3	0.944, 0.331
Percent (%)	0.1	0.0	0.0	
<b>Myocardial infarction</b>				
Frequency	2	1	3	4.948, 0.026
Percent (%)	0.2	0.0	0.0	

categories: general side effects, including fever, local pain, fatigue, and potentially critical side effects, including thrombosis, cardiac, renal, respiratory, and gastrointestinal important symptoms. The most common side effects in our study were general side effects. The prevalence of general complications was 2973 per 10 000 people, the most common of which were fatigue, local pain, and fever in 1957 (17.7%), 1082 (9.8%), and fever 916 (8.3%), respectively. The prevalence of more serious complications was 124 per 10 000 people, which included dangerous complications like arrhythmia (18 cases), pericarditis (3 cases), ataxia (7 cases), and seizures (5 cases). In phase III trial data of Sinopharm vaccine, these were mainly pain at the injection site, followed by

headache.<sup>29</sup> Hataml et al.<sup>30</sup> reported corona vaccine side effects in 2213 Jordanian people: 38%, 31%, and 27% were vaccinated with Sinopharm, AstraZeneca, and Pfizer-BioNTech, respectively. They reported that fatigue, chill, dizziness, and fever were the most common side effects, and however 10% of the cases reported severe side effects. Based on our study, the most common side effect in teenagers is also nonsignificant complications, but the rate of severe adverse reactions in less than 18 years is lesser than in adults. When comparing the results of our study with studies conducted in the age group of children and adolescents, almost similar results have been reported. In Frenck et al.<sup>31</sup> study in the 12- to 15-year-old age group who received the Pfizer vaccine fatigue (66%) and headache (65%) at the injection site were reported as the most common side effects but did not report serious side effects following vaccination. Two RCTs on pediatric population reported mild and transient events, such as injection site pain as the most common side effects,<sup>31,32</sup> but myocarditis and/or pericardium were reported as side effects associated with the COVID-19 vaccine. Cases of inflammation have also been reported in several studies.<sup>33</sup> Nondangerous side effects were more common in our study, although the percentage of these side effects was relatively lower: injection site pain (9.8%), fatigue (17.7%), and fever (8.3%) (Table 5). But in our study, 412 out of 11 042 people who received the vaccine reported potentially dangerous side effects. The study population, type of vaccine injected, and different age ranges could explain the difference.

Breakthrough coronavirus infections happen when someone who was vaccinated for COVID-19 becomes infected with this virus.<sup>34</sup> There are some articles reporting postvaccination infection in adults as Bergwerk et al.<sup>34</sup> reported 39 infections of 1497 fully vaccinated. However, based on our best literature review, we did not find out this information in the pediatric field. In our study, the incidence of COVID-19 after vaccination was 200 of 11 042 cases, and it was significantly lower after the second dose compared to the first dose ( $p < 0.001$ ) (Table 3). *More studies are needed to assess the consequences of vaccines on COVID-19 and maybe last some years.*<sup>35-41</sup>

## 5 | LIMITATIONS

Limitations in our study include the lack of an accurate registration system in medical centers, reliance on telephone reports, and lack of full cooperation by some parents to provide accurate information about their child's illness. Additionally, Soberana (PastoCoVac) vaccine was not granted Emergency Use Listing (EUL) by WHO or FDA, while Sinopharm was granted EUL by WHO and is used in 91 countries (<https://extranet.who.int/pqweb/vaccines/who-recommendation-covid-19-vaccine-bibp>). According to <https://covid19.trackvaccines.org/vaccines/52/>, Soberana (PastoCoVac) vaccine is approved in four countries (Cuba, Iran, Nicaragua, and Venezuela).



**TABLE 8** Start and finish time after developing general side effects following COVID-19 vaccination

Variable	Vaccine type		Total	$\chi^2$ p value
	Soberana	Sinopharm		
General side effects (start)				
On the same day of injection				
Frequency	418	2354	2772	84.666, <0.001
Percent (%)	31.8	24.2	25.1	
The day after the injection				
Frequency	192	1096	1288	
Percent (%)	14.6	11.3	11.7	
Three days after the injection				
Frequency	95	558	653	
Percent (%)	7.2	5.7	5.9	
One week after the injection				
Frequency	28	138	166	
Percent (%)	2.1	1.4	1.5	
Two weeks after the injection				
Frequency	0	34	34	
Percent (%)	0.0	0.3	0.3	
Three weeks after the injection				
Frequency	2	28	30	
Percent (%)	0.2	0.3	0.3	
General side effects (finish)				
On the same day of injection				
Frequency	142	772	914	93.379, <0.001
Percent (%)	10.8	7.9	8.3	
The day after the injection				
Frequency	187	1294	1481	
Percent (%)	14.2	13.3	13.4	
Three days after injection				
Frequency	259	1348	1607	
Percent (%)	19.7	13.9	14.6	
One week after the injection				
Frequency	88	398	486	
Percent (%)	6.7	4.1	4.4	
Two weeks after injection				
Frequency	21	102	123	
Percent (%)	1.6	1.0	1.1	
Three weeks after injection				
Frequency	14	101	115	
Percent (%)	1.1	1.0	1.0	

## 6 | CONCLUSIONS

In conclusion, Sinopharm and Soberana (PastoCoVac) COVID-19 vaccines are generally safe and effective in lesser than 18 years old. Mild, transient general complications were the most common side effects; however, some severe and potentially dangerous side effects were seen and need more consideration. Our data showed that breakthrough infection could occur after full vaccination in teenagers; however, the incidence is significantly reduced after vaccination.

### AUTHOR CONTRIBUTIONS

Nader Tavakoli, Nahid Nafissi, Sanaz Soleimani, and Azadeh Goodarzi contributed to the study idea and design. Morteza Fallahpour, Sanaz Soleimani, Taghi Riahi, and Azadeh Goodarzi conducted database search, literature review, quality evaluation, data gathering, designing, and drafting of the proposal. Rohollah Valizadeh conducted a database search and followed up with the ethical committee for approval, statistics, and analysis. Saeed Kalantari and Alireza Javan contributed to the literature review and drafting of the manuscript, and in the proposal preparation and editing. Azadeh Goodarzi contributed to the supervision of the study. Sanaz Soleimani, Morteza Fallahpour, Sima Shokri, Taghi Riahi, Saeed Kalantari, Alireza Javan, and Azadeh Goodarzi were involved in data collection. All authors contributed to drafting and critical revision of the manuscript for important intellectual content and read and approved the final version to be published and agreed to be accountable for all aspects of the work. They also agreed on the order in which their names are listed in the manuscript.

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### CONFLICT OF INTEREST

The authors declare no conflict of interest.

### DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available from the Iran University of Medical Science (IUMS) but restrictions apply to the availability of these data, which were used under license for the current study, and so are not publicly available. Data are however available from the authors upon reasonable request and with the permission of IUMS.

### ETHICS STATEMENT

The research followed the Tenets of the Declaration of Helsinki. This study was approved by the ethics committee of the Iran University of Medical Sciences (ethical code#IR.IUMS.REC.1400.936). Moreover, informed consent was obtained orally from all the patients.

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