ASTRAZENECA AND SINOPHARM VACCINES ADVERSE EFFECTS AT FIRST AND SECOND DOSES. CROSS SECTIONAL STUDY EGYPTIAN EXPERIENCE

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__Background:__ Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is a novel coronavirus that causes severe acute respiratory syndrome (SARS). It was discovered in December 2019 in Wuhan, China., which subsequently led to a nationwide outbreak. The World Health Organization included the AstraZeneca and Sinopharm vaccines for the WHO Emergency Use List on February 16 and May 7, 2021, respectively. Egyptians have gotten 2,623,200 doses of AstraZeneca's COVID-19 vaccination plus 500,000 doses of Sinopharm vaccine. The trial would test the vaccinations' short-term side effects on Egyptian people aged 18 and older. __Results:__ Most symptoms decreased significantly after the second dose when compared to symptoms seen at the first dose .In addition, both doses reduced symptoms significantly compared to the first dose.Interestingly, the desire to sleep appears to significantly increase the side effects again after both doses when compared to the second dose alone. The majority or nearly all of the participants (96.5%) had no infection after vaccination. __Conclusion:__ Mild to moderate side effects are to be expected after the vaccination process because the body's immunomodulatory instructions can lead to negative symptoms. Symptoms include injection site soreness, fever, tiredness, headache, muscle aches, chills, and diarrhoea.. The majority or nearly all of the participants (96.5%) had no infection after vaccination. Training and continuing education are needed to improve universal vaccine acceptance and reduce frequency.

__Keywords:__ Vaccination, AstraZeneca, Sinopharm, Egyptian population.

INTRODUCTION

SARS-CoV-2, a novel member of the coronavirus family, is the most common cause of severe acute respiratory syndrome (SARS)[1]. First detected in December 2019 in Wuhan City, China, which sparked an epidemic across the country.[1]. The WHO declared the SARS-CoV-2 outbreak to be a pandemic in March of 2020.[2] In Egypt, from January 2020 to July 2021, there were 284, 128 confirmed cases of coronavirus disease (COVID-19) with 16,507 deaths. The rapid spread of the disease, as well as the high death rate of COVID-19 around the world, have prompted many researchers and companies to search for a new vaccine against SARS-CoV-2. The World Health Organization included the AstraZeneca and Sinopharm vaccines for the WHO Emergency Use List on February 16 and May 7, 2021, respectively. Egypt received a total of 2, 623, 200 doses of AstraZeneca vaccine through the Global Access to COVID-19 Vaccines. In addition to 500,000 doses of Sinopharm vaccine from

China[3] .According to the WHO report, a total of 5, 337, 506 doses of vaccine were administered to the Egyptian population, and 1.64 million were fully vaccinated which represents 1.6% of the fully vaccinated population as of July 26, 2021[4]. Vaccination is strongly recommended for health workers at risk of exposure besides the elderly, 65 years of age or older, people with comorbidities and others who are immunocompromised. The AstraZeneca vaccine is only allowed for people over 18 years of age, with an efficacy of 63.09% against COVID-19. It is administered as two intramuscular doses, 8 to 12 weeks apart. On the other hand, Sinopharm showed an efficacy of 79% against symptomatic SARS-CoV-2 infection and hospitalization according to the large, multi-country Phase 3 trial[5]. Sinopharm is given as 2 doses by intramuscular injection at 3-to-4-week intervals between the first and second dose[6]. Mild to moderate side effects are to be expected after the vaccination process because the body's immunomodulatory instructions can lead to negative symptoms. Common side effects include pain at the injection site, fever, fatigue, headache, muscle aches, chills, and diarrhea[7].

In this study, participants over the age of 18 in Egypt were evaluated for the short-term side effects after receiving the first, second, or both doses of AstraZeneca and Sinopharm vaccines.

MATERIAL AND METHODS

Study design

Only the Egyptian population was the focus of a descriptive cross-sectional study. From June 15th to July 15th, 2021, 458 participant are recruited in this study.   . Different governorates of Egypt received this questionnaire (Alexandria (18.7%), El Behira (38.2%), Gharbia (4.4%), Dakahlia (4%), Cairo(4.9%), Fayoum (14.7%), North Sinai (4%), Port said (4%), Sohag (0.4%), Sharqia (0.4%), Monufia (1.8%), Minya (0.4%) & Kafar El Shikh (0.9%)). A three-part survey was created. The first part of the questionnaire asked about the subjects' demographics, their prior exposure to COVID-19, the vaccine they received, and how many doses they received. The second portion dealt with the negative effects of the COVID-19 vaccination following the first and second doses. Participants were asked to choose from symptoms including

fever, fatigue, headache, joint pain, injection site pain, tachycardia, difficult breathing, flu-like symptoms, tremors, desire to sleep and loss of appetite and to mention any other symptoms that they felt after each first or second dose following the vaccination. The 3rd part includes the effect of COVID-19 vaccine on daily activity and post vaccine infection.

Inclusion criteria included administration of at least one dose of AstraZeneca or Sinopharm vaccines. Participants who received a vaccine other than AstraZeneca or the Sinopharm vaccine were excluded. Also, participants who did not receive vaccination against COVID-19 were excluded.

Ethical Consideration

The Ethics Committee at Damanhour University gave its blessing to the current investigation. Taking part in the study was entirely up to the participants. Consent to take part in the research is given by completing the survey.

Statistical Analysis

In the pooled data, the frequency (n) and/or percentage (p) were expressed (percent). For the sake of statistical evaluation, a chi-square test was used. In order to carry out the statistical analysis, we turned to GraphPad Prism® (version 8.4.0, GraphPad Software Inc. At a p-value of 0.05, the findings are considered significant. Minimum sample size was 385 for this survey because of the margin of error and confidence level of 95 percent. According to sample size calculation , we projected that 50 percent of the population had side effects (FDA-reported side effects ranged from 14.2 percent to 84.1 percent). The COVID-19 vaccine questionnaire was completed by 458 participants in this study.

RESULTS AND DISCUSSION

Results
COVID-19 post-infection demographics, vaccine type, and number of vaccine doses are all included in table 1

This study included 458 adult Egyptian participants, most of them were females (n= 458, 56%), while 44% were males. Additionally, the past medical history of participants revealed that, most of enrolled participants (n= 316, 69%) had never been infected, while (n= 142, 31%), had been

infected with the SARS-CoV-2 virus. Regarding, Type of COVID-19 vaccine, more than half of the studied participants (n= 258, 56%) had received AstraZeneca vaccine, and (n=200, 44%) had received Sinopharm vaccine. Also, (n= 246, 54%) had received the first dose only of vaccine, and (n= 212, 46%) had received both doses of vaccine, as shown in table (1).

In this study, 40% of the participants were aged 30- 40 years, 36.6% were 18-30 years old, 13.3% were 40-50 years old, 9.3% were 50-60 years old while 5.8% were older than 60 years old. Also, 68.9% of the participants belonged to the medical team while 31.1% belonged to the non-medical team. Most of the Egyptian governments were included in this study, where most of the participants belonging to Beheira government with a percentage (n= 178, 38.86%), as shown in figure 1 (1A, 1B and B: Distribution of speciality C: Distribution by the governorate

Table 1: Demographic data of the studied patients

Variables	The studied patients (n= 458)	
	No.	%
Nationality		
• Egyptian	458	100%
• Non-Egyptian	0	0.00%
Sex		
• Male	200	44.00%
• Female	258	56.00%
Previous infection with COVID-19 before vaccine		
• Infected	142	31.00%
• Not-Infected	316	69.00%
Type of COVID-19 vaccine		
• Sinopharm vaccine	200	44.00%
• AstraZeneca vaccine	258	56.00%
Inoculated vaccine dose		
• First dose only	246	54.00%
• First and second dose	212	46.00%

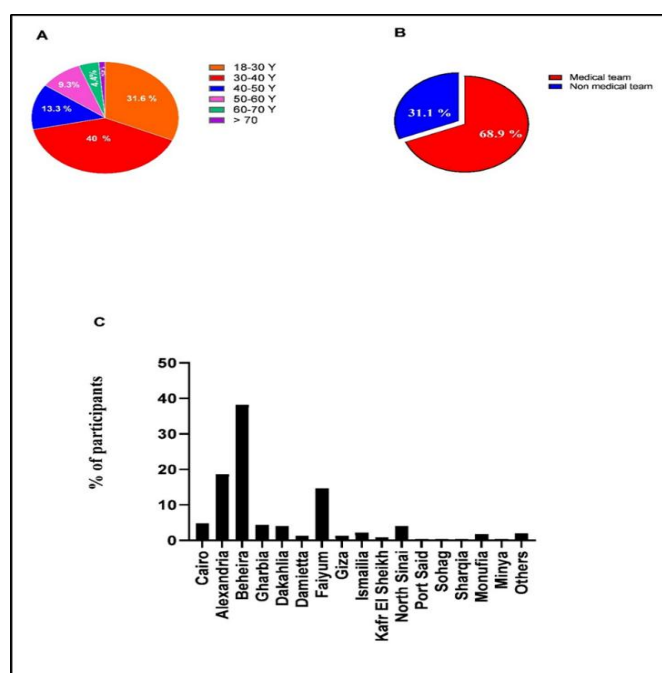**Note**: Results were expressed as frequency (n) and percentage (%).

Fig. 1: Distribution of participants according on their age, specialty, and government agency. A: Distribution of ages. B: Distribution of speciality . C: Distribution by the governorate.

COVID-19 Vaccine Side Effects

The presence of side effects after the COVID-19 vaccine was significantly increased among study participants after receiving their first dose of the vaccine (n= 272, 59.40%) compared to receiving their second dose (n= 76, 24%) and receiving both doses (n=52, 19.1%), meaning that there was a significant decrease after both doses when compared to the other doses alone (P< 0.001).

Side effects such as fever or high temperature, tiredness, headache, joint pain, injection site pain, tachycardia, difficulty breathing, flu-like symptoms, tremors, sleeplessness, and loss of appetite increased significantly after taking the first dose of the drug. Second and subsequent doses were compared to the number of participants who experienced the same side effects. Disturbingly, however, there were no significant differences between the three trial groups in terms of symptoms such as diarrhea , a sore throat, nausea–and vomiting, and a loss of smell or taste. Interestingly, sleep craving shows a significant increase in side effects again after both doses when compared to the second dose alone (P> 0.05), as shown in (Table 2& Fig 2).

Table 2: First, Second, and Both Doses of the COVID-19 Vaccine's Side Effects, and Their Correlation.

	Studied patients			
	First dose (n=458)	Second dose (n=314)	First and second dose (n= 272)	*P* Value
Presence of Symptoms				
Presence	272(59.40%)	76 (24.00%)	52 (19.10%)	
Absence	186(40.60%)	238 (76.00%)	220 (80.90%)	<0.001*
Associated Symptoms				
Fever	194(42.30%)	34(10.83%)	16(5.88%)	<0.001*
Fatigue	250(54.60%)	56(17.83%)	8(2.94%)	<0.001*
Headache	162(35.40%)	24(7.64%)	8(2.94%)	<0.001*
Joint Pain	124(27.10%)	16(5.10%)	4(1.47%)	<0.001*
Injection site pain	262(57.20%)	76(24.20%)	60(22.11%)	<0.001 *
Diarrhea	16(3.56%)	8(2.55%)	2(0.74 %)	0.28
Tachycardia	42(9.33%)	4(1.27%)	2(0.74%)	0.006*
Difficulty breathing	26 (5.68%)	6(1.91%)	2(0.74%)	0.02 *
Flu-Like symptoms	36(7.86%)	6(1.91%)	6(2.21%)	0.007*
Tremors	74(16.16%)	4(1.27%)	2(0.74 %)	<0.001*
Sore throat	18 (3.93%)	6(1.91%)	2(0.74 %)	0.15
Desire to sleep	124(27.10%)	28(8.92%)	38(13.97%)	<0.001 *
Loss of appetite	24(5.24%)	2(0.64%)	2(0.74 %)	0.006*
Loss of sense of smell	2(0.44%)	2 (0.64%)	2(0.74 %)	0.93
Loss of sense of taste	2(0.44%)	2(0.64%)	2(0.74 %)	0.93
Blurred vision	16(3.56%)	2(0.64%)	2(0.74 %)	0.067
Vomiting	6(1.31%)	2(0.64%)	2(0.74 %)	0.76

Data were expressed as frequency (n) and percentage (%). The correlation between variables was tested and compared using Chi-Square test and results considered as significant at level less than 0.05. *Significant difference at p< 0.05.
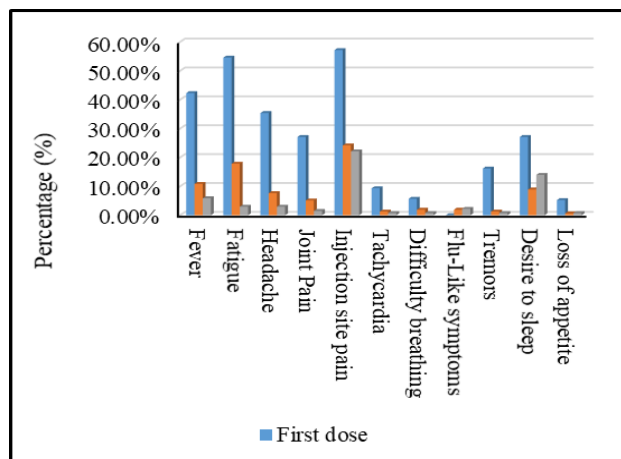

Fig 2: Reported COVID-19 Vaccine side effects after first, second and both vaccine doses.

Effect of COVID-19 Vaccine on daily activity and Post Vaccine infection:

The COVID-19 vaccine affected daily activity in most participants (n= 282, 61.6%), while (n= 176, 38.4%) participants showed no effect at all on their daily activity. Also, post-COVID-19 vaccine infection with SARS-CoV-2 virus. The majority or nearly all participants (n= 442, 96.5%) had no infection after vaccination. On the other hand, only (n = 12, 2.6%) of the participants were infected with SARS-CoV-2 after vaccination with the first dose, while only four (0.9%) participants were infected after a second dose of vaccine, as shown in figure 3 (3A and 3B).

The COVID-19 pandemic continues to threaten the world. The vaccination offers a major hope for controlling viral infection. There are now several coronavirus vaccinations. To be effective, a vaccination must be acceptable and used by the majority of the population[8].

The questionnaire includes questions regarding the participant's MERS-CoV illness experience, health beliefs about MERS-CoV and its vaccine, and general knowledge, attitudes, and practices about the vaccine. Individuals working in the medical industry had a larger percentage of females than other jobs. So, females have more worries, are more susceptible to in infection, and want to share and test their knowledge of the coronavirus vaccine.

The first step in supporting public education is to find out why. General understanding of disease transmission, prevention, and vaccine information is essential to increase vaccine acceptability and decrease vaccination frequency in the public to eliminate coronavirus infection[9].
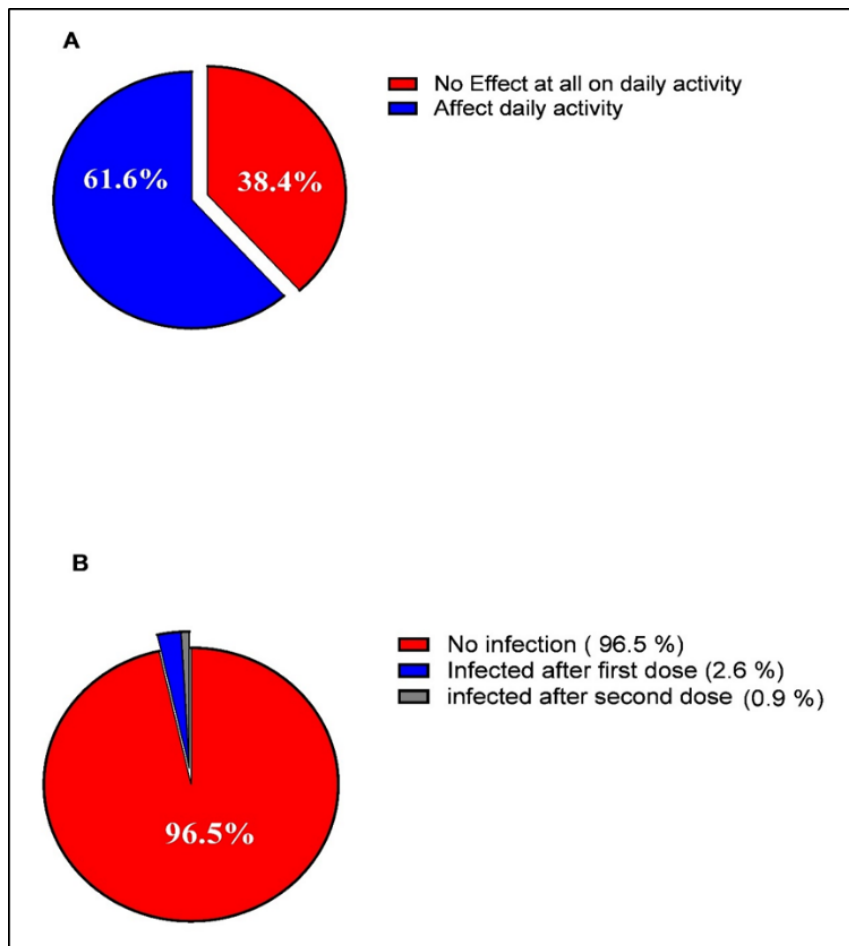

Fig 3: Effect of COVID-19 Vaccine (Astrazeneca) on daily activity and post vaccine infection. A: Effect on daily activity. B: Post Vaccine infection.

Also, the study by Elgendy and Abdelrahim,[10] revealed that, The study enrolled 871 people, 465 of them female. Most were in the 35-45 age range (44.8%). 63.8% are married and have college degrees. 74.1% lived in cities and 50% worked in non-medical vocations. The majority of participants (89.2%) said they had the coronavirus. 89 % of subjects had a coronavirus-infected in a close relative. 54% have a family member hospitalized due to a coronavirus infection. 89% said a person can get a coronavirus infection more than once. 62% feel that herd immunity is adequate to protect everyone against the Corona virus, and 79% believe that immunity from infection is better than vaccination immunity.

Another study by Saied *et al.,*[11] included 2133 students from Tanta and Kafr-Elshekh universities, with a mean age of 20.24 ± 1.8 years. Acceptance was 34.9% (746 out of 2133), hesitation was 45.7 percent (974 out of 2133), and refusal was only 19.4 percent (413 out of 2133). Factors linked with medical students' adoption of the COVID-19 vaccine: With regard to these factors, there was no statistically significant difference between groups of students who accepted, reluctant, or declined the immunization. The study included 760 females and 320 males. The participants' mean age was 37.22 13.1. Around 508 (47%) are employed, 232 (21.5%) are unemployed, and 304 (28.1%) are students.

Also, the study by Elgendy and Abdelrahim,[10] revealed that, Post-COVID-19 syndromes included fatigue, depression, high blood sugar, inflammation or redness in the eyes, blood clots, and shortness of breath, cough, chest pain, difficulty concentrating or thinking, increased heart rate, 16.2% hair loss, 27% nausea, and 32.4 % inflammation or redness in the eyes. However, 24.3% had no post-COVID-19 symptoms. Coronavirus killed 48.5% of the participants' relatives. The bulk of individuals (81%) still take precautions against SARS-CoV-2 infection.

Another study by Lucia *et al.,*[12] indicated that vaccination hesitation was due to concerns about major adverse effects and lack of reliable information. Concerns about long-term side effects, safety, and vaccination mistrust also lead to vaccine hesitancy according to Tam *et al.,*[13].

In response, many people fear vaccination, overestimating possible negative effects[14]. Many reluctant persons are anticipated to

embrace vaccination if informed that it is safe and effective.

Furthermore, the studies by Xia *et al.,*[15] and WHO,[16] revealed that, no side effects were reported by 24.4 percent (26 vs. 18.6%). A substantial difference between the two groups (49 years vs> 49 years) with severe pain was observed. Nausea (P = 0.010) and myalgia (P= 0.010) were seen after the vaccination. The prevalence of severe pain at the vaccination site, nausea, and muscle pain was significantly different between the two groups after the first dose of immunization. While tiredness prevalence was found to differ between groups in the second dose. Defined as usual pain at the vaccination site (42.2%), weariness (12.2%), headache (9.5%), lethargy (9.5%), and muscle pain (5.2%) (6.3 percent). Subjects in phase 1/2 of the Sinopharm vaccine experiment had similar symptoms to our research participants. According to Sinopharm, the vaccine caused injection site reactions and headaches. Anxiety, fatigue, and soreness at the immunisation site were reported as common adverse reactions that were self-limited and recovered.

Rumors, questions, hesitancy, and rejection have hampered COVID-19 vaccination campaigns. The harmful effects of vaccines have also been over-reported, although some of these symptoms are normal physiological processes or developmental anomalies unrelated to any medicine including immunizations . Some claimed side effects as typical physiological processes like teething, whereas others observed growths like a split tongue.[17] Monitoring the safety of COVID-19 vaccines is an important and ongoing process that must also be disciplined. In the United States, the vaccine adverse event reporting system was implemented as an active surveillance system, during the initial implementation phases of the COVID19 National Vaccination Program[18]. The continuing and careful safety monitoring of COVID-19 vaccinations is critical. The vaccine adverse event reporting system was implemented as an active surveillance system during the COVID19 National Vaccination Program's early implementation phases.[19]

By April 15, 2021, Jordan has given at least 524,533 doses of COVID-19 vaccine, enough to immunise roughly 2.6 percent of the population[18].

Unfortunately, little research on COVID-19 clinical outcomes has been published in

Jordan, and no research on vaccination efficacy or safety has been undertaken there to far. Using three vaccines allowed us to collect as many responses as possible and analyse potential changes in interactions between the first and second doses. Reassuring vaccine recipients by collecting evidence-based data on local and systemic SE is critical at this critical stage of the vaccination campaign, especially if these effects are transient or temporary, as this may alleviate concerns and encourage future vaccination with two sequential and booster doses. a need[20].

Additionally, the study by Abu-Hammad et al.,[18] revealed that, The reduced risk of side effects in the second dose receivers may be attributed to the number of different vaccine recipients between the first and second dose recipients in their study. Less than 4% of second-dose patients received the AZ vaccination, which has been linked to severe side effects. Some participants reported gastrointestinal (nausea, vomiting, diarrhoea) and respiratory (dyspnea) side effects, as well as ear, face, and diuretic symptoms.

Approximately 45% of second-dose patients received the SP vaccine, which had the fewest side effects. The COVID-19 vaccines commonly cause side effects such as soreness, swelling, and redness at the injection site, exhaustion, chills, fever, muscle discomfort, headache, and nausea.[21]

Because vaccine acceptance influences the implementation of mass vaccination campaigns and consequently the control of the current pandemic, the following strategies are recommended: Providing evidence-based information on COVID-19 vaccines through proactive and highly managed programmes. To provide honest and understandable information to reduce confusion and suspicion and rebuild a relationship of trust with the public using social and traditional media, as well as to monitor disinformation and fake news on COVID-19 vaccines, especially on platforms social media.

Conclusions

Participants in the study were well-informed on MERS-CoV and the vaccine that protects against it. However, despite participants' satisfaction with the vaccine's acceptance, there were some worries about it due to a lack of clinical trials and the possibility of negative side effects. Participants prefer Sinopharm over Astrazeneca vaccine, as Sinopharm had no effect on the daily activities of subjects. Vaccine information is critical, and it should not be withheld. Continuing education and training are necessary to improve vaccine acceptance and minimize vaccination rates.

Conflict of Interest
The authors declare that they have no conflict of interest.

Data availability
Data available on request from the authors.

This study was performed in line with the principles of the Declaration of Helsinki. Approval was granted by the Ethics Committee of University of Damanhur

Recommendations
Because vaccine acceptability is linked to mass vaccination campaigns and thus pandemic control, the following approaches are advocated to promote vaccine adoption:
- Provide evidence-based information for COIVID-19 vaccines with proactive measures to combat misinformation.
- Using social and traditional media to engage expert groups of health professionals and scientists on COVID-19 vaccinations to deliver honest and understandable information to reduce uncertainty and distrust.
- Monitor and correct disinformation about COVID-19 vaccinations, particularly on social media.

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نشرة العلوم الصيدليـــة

جامعة أُسيوط

الآثار السلبية للقاح الاسترازينيكا وسينوفارم في الجرعات الاولي والثانية

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فيروس كورونا هو فيروس كورونا جديد يسبب المتلازمة التنفسية الحادة الوخيمة (سارس). تم اكتشافه في ديسمبر ٢٠١٩ في ووهان ، الصين ، مما أدى لاحقًا إلى تفشي المرض على مستوى البلاد. أدرجت منظمة الصحة العالمية لقاحا استرازينيكا و سينوفارم لقائمة الاستخدام الطارئ لمنظمة الصحة العالمية في ١٦ فبراير و ٧ مايو ٢٠٢١ ، على التوالي. حصل المصريون على ٢٦٢٣٢٠٠ جرعة من لقاح أسترازينيكا. بالإضافة إلى ٥٠٠٠٠٠ جرعة من لقاح سينوفارم.

ستختبر التجربة الآثار الجانبية قصيرة المدى للتطعيمات على المصريين الذين تبلغ أعمارهم ١٨ عامًا فأكثر.

أثبتت النتائج انخفاض معظم الأعراض بشكل ملحوظ بعد الجرعة الثانية مقارنة بالأعراض التي تظهر عند الجرعة الأولى. بالإضافة إلى ذلك ، انخفضت الأعراض بعد كلتا الجرعتين بشكل ملحوظ عند مقارنتها بالأعراض عند الجرعة الأولى. ومن الملحوظ ايضـا أن الرغبة في النوم يبدو أنها تزيد بشكل كبير من الآثار الجانبية مرة أخرى بعد كلتا الجرعتين عند مقارنتها بالجرعة الثانية وحدها. غالبية أو جميع المشاركين تقريبًا (٩٦.٥٪) لم يصابوا بأي إصابة بعد التطعيم.

من المتوقع حدوث آثار جانبية خفيفة إلى معتدلة بعد عملية التطعيم لأن تعليمات تنظيم المناعة في الجسم يمكن أن تؤدي إلى أعراض سلبية. تشمل الأعراض وجع مكان الحقن ، والحمى ، والتعب ، والصداع ، وآلام العضلات ، والقشعريرة ، والإسهال . الغالبية أو جميع المشاركين تقريبًا (٩٦.٥٪) لم يصابوا بأي عدوى بعد التطعيم.

وبناء علي النتائج السابقة فأنه من المهم تقديم معلومات كافية عن التطعيمات. هناك حاجة إلى التدريب والتعليم المستمر لتحسين القبول الشامل للقاح وتقليل التكرار.