DOI: https://doi.org/10.17816/brmma80760
Scientific article

EVALUATION OF VACCINE "SPUTNIK V" IMMUNOGENICITY AND REACTOGENICITY WHEN IT IS USED IN MILITARY PERSONNEL

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ABSTRACT: The article presents the results of a study of the immunogenicity and reactogenicity of the vaccine Gam-COVID-Vac (Sputnik V) when used in military personnel undergoing military service on conscription. From 300 military personnel consistently vaccinated with one and two components of Gam-COVID-Vac at the intervals of 21 days, blood serum was obtained and examined three times: before vaccination, and 30 and 60 days after the introduction of the first component of the vaccine. In the blood serums, the content of Class G antibodies to the SARS-CoV-2 was determined by the method of solid-phase enzyme immunoassay. After immunization with the Gam-COVID-Vac vaccine, the average geometric titer of Class G antibodies to SARS-CoV-2 -in the blood serum of a military personnel obtained during the second and third examinations (5.02 $\log^2$ and 5.67 $\log^2$) increased by 2.4 and 2.7 times, respectively ($p < 0.05$), compared to the same indicator before the vaccination (2.11 $\log^2$). Total of 30 days after the introduction of the first component of the vaccine (Nine days after the introduction of the second component of the vaccine), Class G antibodies to the new coronavirus SARS-CoV-2 were detected in the 86.7% of military personnel, and after 60 days — in 92% of vaccinated. Studies have revealed moderate reactogenicity of the vaccine. Moreover, the proportion of postvaccination reactions in the first 3–5 days after the introduction of the second component of the vaccine was less after the introduction of the first component of the vaccine. So, if after the introduction of the first component of the vaccine, an increase in body temperature > 37 °C was observed in 20% of military personnel, then after the introduction of the second component only in 9%, and the share of local reactions decreased from 9–4%. There have been no cases of serious adverse events after immunization of military personnel with the Gam-COVID-Vac vaccine.

Keywords: coronavirus; vaccination; conscripts; Gam-COVID-Vac (Sputnik V); Class G antibodies; immunogenicity; reactogenicity; post-vaccination reactions.

To cite this article:
Zhogolev SD, Gorenchuk AN, Kuzin AA, Kulikov PV, Zhogolev KD, Apchel VYa, Sergeev TS, Lantsov EV, Artebyakin SV, Zharkov DA. Evaluation of vaccine "Sputnik V" immunogenicity and reactogenicity when it is used in military personnel. *Bulletin of the Russian Military Medical Academy.* 2021;23(4):147–152. DOI: https://doi.org/10.17816/brmma80760

Received: 21.09.2021 **Accepted:** 28.11.2021 **Published:** 20.12.2021

ECO•VECTOR

УДК 614.47
DOI: https://doi.org/10.17816/brmma80760
Научная статья

ОЦЕНКА ИММУНОГЕННОСТИ И РЕАКТОГЕННОСТИ ВАКЦИНЫ «СПУТНИК V» ПРИ ЕЕ ПРИМЕНЕНИИ У ВОЕННОСЛУЖАЩИХ

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Резюме. Представлены результаты исследования иммуногенности и реактогенности вакцины «Гам-КОВИД-Вак» («Спутник V») при ее применении у военнослужащих, проходящих военную службу по призыву. Исследование проводилось по распоряжению вышестоящего командования с учетом эпидемических показаний. От 300 военнослужащих, последовательно вакцинированных первым и вторым компонентами «Гам-КОВИД-Вак» с интервалом в 21 день, были трижды получены и исследованы сыворотки крови: до вакцинации и через 30 и 60 дней после введения первого компонента вакцины. В сыворотках крови определяли содержание антител класса G к вирусу SARS-CoV-2, используя твердофазный иммуноферментный анализ. После иммунизации вакциной «Гам-КОВИД-Вак» средний геометрический титр антител класса G к SARS-CoV-2 в сыворотках крови военнослужащих, полученных при втором и третьем обследованиях (5,02 $\log^2$ и 5,67 $\log^2$), возрос по сравнению с аналогичным показателем до вакцинации (2,11 $\log^2$) в 2,4 и 2,7 раза соответственно ($p < 0,05$). Через 30 дней после введения первого компонента вакцины (через 9 дней после введения второго компонента вакцины) антител класса G к новому коронавирусу SARS-CoV-2 выявлены у 86,7% военнослужащих, а через 60 дней — у 92% вакцинированных. Показана умеренная реактогенность вакцины. Причем доля поствакцинальных реакций в первые 3–5 суток после введение второго компонента вакцины была меньше, чем на введение первого компонента вакцины. Так, если после введения первого компонента вакцины повышение температуры тела выше 37 °С наблюдалась у 20% военнослужащих, то после введения второго компонента только у 9%, а доля местных реакций снизилась с 9 до 4%. Случаев серьезных побочных проявлений после иммунизации военнослужащих вакциной «Гам-КОВИД-Вак» не выявлено.

Ключевые слова: коронавирус; вакцинация; военнослужащие по призыву; Гам-КОВИД-Вак (Спутник V); антитела класса G; иммуногенность; реактогенность; поствакцинальные реакции.

Как цитировать:
Жоголев С.Д., Горенчук А.Н., Кузин А.А., Куликов П.В., Жоголев К.Д., Апчел В.Я., Сергеев Т.С., Ланцов Е.В., Артебякин С.В., Жарков Д.А. Оценка иммуногенности и реактогенности вакцины «Спутник V» при ее применении у военнослужащих // Вестник Российской военно-медицинской академии. 2021. Т. 23, № 4. С. 147–152. DOI: https://doi.org/10.17816/brmma80760

Рукопись получена: 21.09.2021 **Рукопись одобрена:** 28.11.2021 **Опубликована:** 20.12.2021

ЭКО • ВЕКТОР

BACKGROUND

The causative agent of a new coronavirus infection (SARS-CoV-2 virus) was first discovered in the biomaterial of patients with community-acquired pneumonia in Wuhan, the People's Republic of China, at the end of 2019 [1–3]. Subsequently, the coronavirus quickly spread to all continents. The high intensity of human population migration was responsible for such rapid propagation.

Because military teams share common living conditions, service, and life, several military personnel are actively involved in the epidemic. Therefore, more cohorts must be studied to obtain objective data on the immunological aspects of SARS-CoV-2 coronavirus infection, including in military teams [4–6].

Vaccination is the foundation for preventing a new coronavirus infection [7–8]. The Gam-COVID-Vac vaccine (Sputnik V) developed at Russia's Ministry of Health's N.F. Gamaleya National Research Center of Epidemiology and Microbiology was the world's first vaccine against COVID-19. It was first registered in August 2020. Clinical trials showed that it was 91.6% effective [9]. Currently, the drug is approved for use in 70 countries.

Since January 2021, the Russian Federation's Armed Forces have mass-immunized military personnel with this vaccine.

This study examines the immunogenicity and reactogenicity of the Gam-COVID-Vac vaccine when used in a military team.

MATERIALS AND METHODS

We analyzed data from a survey of young recruits conducted by specialists from the Russian Ministry of Defense's Center 985 for State Sanitary and Epidemiological Surveillance in the North-West region from January to March 2021. The S.M. Kirov Military Medical Academy's local ethics committee approved the study's protocol. The Gam-COVID-Vac combined vector vaccine was used for vaccination (manufacturer of the finished dosage form International Innovative Biotechnology Company of the full cycle BIOKAD). Components 1 and 2 of the vaccine were administered at a dosage of 0.5 ml intramuscularly into the deltoid muscle at intervals of 21 days.

Blood serum was collected three times from 300 soldiers vaccinated with both Gam-COVID-Vac components and tested before, 30, and 60 days after component 1 of the vaccine was administered. The content of class G antibodies (IgG) to the SARS-CoV-2 virus in blood sera was determined using enzyme-linked immunosorbent assay (ELISA) on a photometer for microplates model 680 (Model 680 Microplate Reader) with a set of reagents for qualitative and semi-quantitative enzyme immunoassay for the detection of IgG to coronavirus SARS-CoV-2 in human serum and plasma SARS-CoV-2IFA-IgG series E004. Post-vaccination reactions were recorded following the administration of each component of the vaccine.

All the individuals examined were called up for military service between the ages of 18 and 20 in November 2020. According to the recruitment criteria for conscripted soldiers to the training center in the autumn of 2020, none had previously had COVID-19. All patients polled gave their informed consent to participate in the study. Military personnel received theoretical training in classrooms before and for 60 days following vaccination.

The positivity index (PI) was used to determine the titers of IgG antibodies in the test blood serum sample, according to the instructions for the reagent kit. The PI was calculated as the ratio of the sample's optical density (OD) to the critical OD (OD of the negative control sample + the coefficient specified in the instructions for this series of reagents). If the sample PI was less than 0.9, it was assumed the test sample lacked IgG antibodies to the SARS-CoV-2. When the sample PI was from 0.9 to 1.1, the result was considered doubtful, and the test sample was seronegative. In these cases, the IgG antibody titer was conventionally assumed to be 1:5. PI of 1.1 or greater indicated the presence of immunoglobulins G, namely with PI of 1.1–2.5, it was assumed that the antibody titer was within the range of 1:10/1:20; PI of 2.6–5 corresponded to an antibody titer of 1:40, and PI of 5.1 to 6.5 corresponded to an antibody titer of 1:80. With a PI of 6.6 or higher, the blood serum was diluted 10 times with a buffer solution. Diluted serum PI from 1–1.9 corresponds to an antibody titer of 1:100, 2–3 to a titer of 1:200, 3.1–4 to a titer of 1:400, and so on.

ELISA was used to examine 900 blood serum samples in total. After the laboratory studies, the geometric mean titers of IgG antibodies in the blood sera of vaccinated military personnel obtained during each of the three examinations were calculated, and the indicators obtained were analyzed.

Post-vaccination reactions were observed after each component of the vaccine was administered. To determine vaccine reactogenicity, a medical worker of the training center conducted a survey and examination of military personnel daily at 08:00 and 21:00 for the presence of local and general post-vaccination reactions. The soldiers' body temperatures were taken three times a day before meals. Soldiers with a body temperature above 37°C were under medical supervision at the training center's medical aid station.

Nominal data were described in absolute values, whereas derived data were described in percentages and logarithms (Microsoft Excel 2010 and Statistica 10.0). A parametric correlation analysis was performed on the data using the Student's *t*-test. The significance of differences in indicators was determined using the probability level $p \leq 0.05$.

RESULTS AND DISCUSSION

The local and general post-vaccination reactions were noted in the first 3–5 days after the administration of

the vaccine component 1 and 21 days after the administration of component 2; namely, pain, swelling, and redness at the injection site were registered in 9% of the military personnel who received the vaccine component 1, and in 4% after the administration of component 2; an increase in body temperature up to 38°C was noted in 14% and 7%, respectively, while that over 38°C was detected in 6% and 2% of cases; ailment and headache were registered in 19% and 6% of the patients examined. There were no reports of serious side effects after military personnel were immunized with both components 1 and 2 of the vaccine.

In blood serum obtained prior to vaccination, 123 (41%) of 300 military personnel did not have IgG antibodies to SARS-CoV-2, and the antibody titer was less than 1:5 in 71 (23.7%) patients (doubtful). As a result, 194 (64.7%) of the soldiers were seronegative prior to vaccination. Antibody titers were insignificant in 106 (35.3%) patients, ranging from 1:10 to 1:20. (Fig. 1).

Before vaccination, the geometric mean titer of antibodies to SARS-CoV-2 in soldiers' blood sera was 2.11 $\log^2$ (Fig. 2).

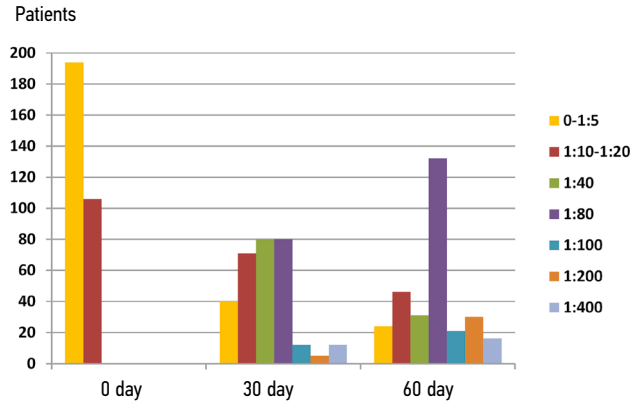

Fig. 1. Distribution of a military personnel in the group of vaccinated by the content of antibody titers against COVID-19
Рис. 1. Распределение военнослужащих в группе вакцинированных по содержанию титров антител против COVID-19

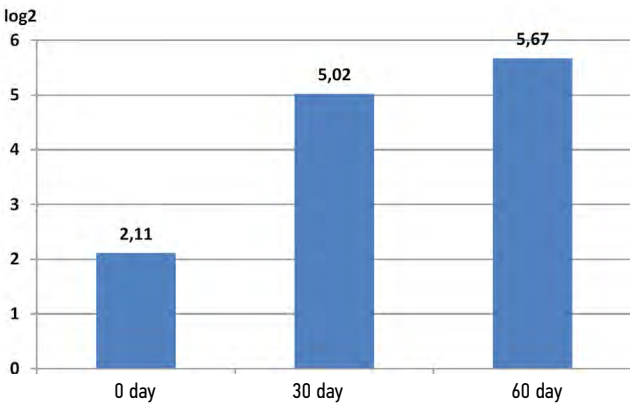

Fig. 2. Average geometric titers of the antibodies against COVID-19 in the blood sera of military personnel before and after the vaccination ($\log^2$) Рис. 2. Средние геометрические титры антител против COVID-19 в сыворотках крови военнослужащих до и после вакцинации ($\log^2$)

Blood samples 2 were collected thirty days after administering vaccine component 1 (on day 9 after administering the component 2). Titers of antibodies to SARS-CoV-2 in blood serum were not determined in 40 (13.3%) patients. Antibody titers 1:10–1:20 were found in 71 (23.7%) of the patients, titers 1:40 in 80 (26.7%) of the patients, titers 1:80 in 80 (26.7%) of the patients, 1:100 in 12 (4.0%) of the patients, 1:200 in 5 (1.7%) of the patients, and 1:400 in 12 (4.0%) of the patients. Thus, 86.7% of military personnel had IgG antibodies to the new SARS-CoV-2 coronavirus during the examination. One month after vaccination, the geometric mean titer of antibodies to SARS-CoV-2 in soldiers' blood sera was 5.02 $\log^2$.

Only 24 (8%) vaccinated soldiers had an antibody titer in their blood serum on day 60 after starting immunization, according to studies of blood samples 3. Antibody titers ranged from 1:10 to 1:20 in 46 (15.3%) of the patients. Antibody titers of 1:40 were found in 31 (10.3%) of the patients, 1:80 in 132 (44.0%), 1:100 in 21 (7.0%) of the patients, 1:200 in 30 patients (10.0%), and 1:400 in 16 (5.3%) of the soldiers. Thus, IgG antibodies to the new SARS-CoV-2 coronavirus were detected in 92% of military personnel during examination 3, which was conducted 60 days after the administration of component 1 of the vaccine (39 days after the administration of component 2 of the vaccine). The geometric mean titer of SARS-CoV-2 antibodies in soldiers' blood sera 2 months after vaccination was 5.67 $\log^2$.

According to the instructions for the test systems, the titer of antibodies to SARS-CoV-2 in the blood sera of 194 (64.7%) military personnel before immunization was not determined, and in 106 (35.3%) military personnel, it was estimated as low (1:20/1:80) (Fig. 3). Prior to vaccination, no patients in the studied group had higher antibody titers.

Thirty days after immunization, the number of military personnel lacking antibodies to SARS-CoV-2 decreased to 40 (13.3%), the number of military personnel with a low antibody titer (1:20/1:80) increased to 231 (77%), and

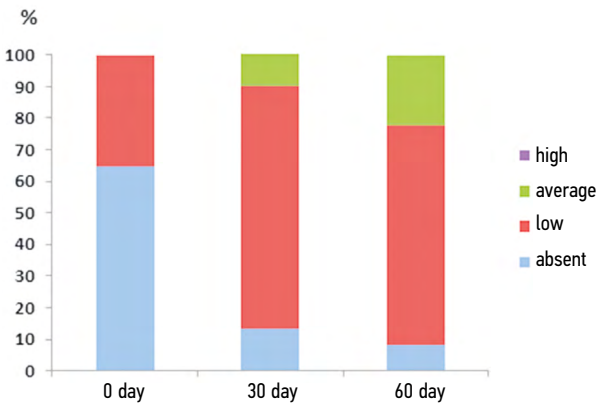

Fig. 3. Dynamics of the structure of the level of antibodies to SARS-CoV-2 in vaccinated military personnel
Рис. 3. Динамика структуры уровня антител к SARS-CoV-2 у вакцинированных военнослужащих

DOI: https://doi.org/10.17816/brmma80760

29 (10%) soldiers had an average level of antibody titer (1:100/1:400). Sixty days after immunization, the number of seronegative military personnel fell to 24 (8%), low levels of antibodies were detected in 209 military personnel (69.7%). The average level was detected in 67 (22.3%). During the study period and for the next two months, there were no cases of COVID-19 among vaccinated military personnel.

The vaccine was found to be moderately reactogenic in the studies. Furthermore, the proportion of post-vaccination reactions was lower in the first 3–5 days after vaccine component 2 administrations than after vaccine component 1. Hence, if an increase in body temperature above 37°C was recorded in 20% of military personnel following the administration of vaccine component 1, it was only in 9% of cases following the administration of component 2, and the proportion of local reactions decreased from 9% to 4%. There have been no reports of severe side effects following the Gam-COVID-Vac vaccination of military personnel.

After vaccination, the proportion of patients who did not have IgG antibodies to SARS-CoV-2 decreased from 64.7% to 13.3% (a decrease of 4.9 times) 30 days after administering vaccine component 1 (9 days after the administration of vaccine component 2). It decreased up to 8% (a decrease of 8.1 times) 60 days after the start of vaccination ($p < 0.001$).

Thus, after 30 days of vaccination, IgG antibodies to the new SARS-CoV-2 were detected in 86.7% of military personnel and 92% of those vaccinated after 60 days.

IgG antibodies in one-third of military personnel (35.3%) prior to vaccination indicate that these individuals had a coronavirus infection in the past, either as an asymptomatic infection or as acute respiratory diseases or other diagnoses.

The geometric mean titer of antibodies to SARS-CoV-2 in the blood sera of vaccinated patients, obtained at examinations 2 and 3 (5.02 $\log^2$ and 5.67 $\log^2$), increased by 2.4 and 2.7 times, respectively, compared to the same indicator obtained at examination 1 (2.11 $\log^2$) ($p < 0.05$).

The data obtained indicate that the Gam-COVID-Vac vaccine has high immunogenicity with moderate reactogenicity when used in cons, which corresponds to the data obtained during its clinical trials [4].

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