

Sputnik v: is the Russian Vaccine Safe?

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ABSTRACT

Sputnik V was the world's first vaccine against the new coronavirus to be registered by a world health entity. The Russian immunizing agent is a vaccine based on adenovirus, which worries some international authorities due to the possibility of an interaction between the vaccine vector and the immune system of those vaccinated. Even after the publication of the results of phase 3 of the vaccine studies, there are several discussions about the safety and effectiveness of the vaccine, which call into question whether or not the vaccine should be made available around the world.

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In March 2020, after WHO declared a pandemic state for SARS-CoV-2, several pharmaceutical companies and research institutes around the world started the development of immunizers that would impede the development of COVID-19. In August of the same year, Sputnik V was the first vaccine in the world against the new coronavirus to receive registration from a health entity in the world, even though only two of the three phases of vaccine development had been completed and were published in September [1]. This vaccine was developed by the Gamaleya Research Institute of Epidemiology and Microbiology, with the Russian government as its main source of funding, which has stirred up the political debate around the efficacy and safety of the vaccine [2].

The Russian vaccine is among the 3 vaccines with efficacy above 90%, along with the Pfizer-Biotech (95%) and Modern (94.5%) vaccine. The ease of storing the vaccine and its low cost (below 10 dollars) are factors that make it possible to purchase immunization agents, especially in the poorest countries. Sputnik V is a safe vaccine, but it can lead to adverse effects like other vaccines from other manufacturers. These reactions must be monitored and promptly reported. More long-term efficacy studies must be conducted to access the real effectiveness of the Russian vaccine [3].

Sputnik V is a brewed adenovirus-based vaccine. Adenoviruses carry the necessary genetic material for the production of antibodies against the protein S of SARS-CoV 2, as shown in

Figure 01. The non-replicating adenoviruses used by the vaccine are harmless to humans. The technology used in this vaccine has been used for decades. 2 different adenoviruses are used (AD16 and AD5), 1 in each dose of vaccine and must be 21 days interval. The same technology is used by other vaccines such as AstraZeneca Oxford.

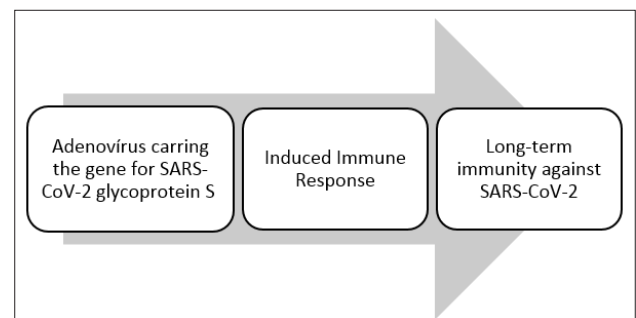


Figure 1: Mechanism of immune response induction by Sputnik V
Source: Own Authorship

The results of Phase 3 of the Russian vaccine were published in February 2021 in The Lancet. The study had 19.866 volunteers who received the 2 doses of vaccine. 2.144 elderly people participated in the study. Among the main results reported, the vaccine efficacy rate was 91.6% for any form of COVID-19, the main results of the study are shown in Figure 02. The levels of neutralizing antibodies against SARS-CoV-2 were 1.3 to 1.5 times higher in participants who received the Sputnik vaccine V than in patients who recovered from COVID-19 [4].

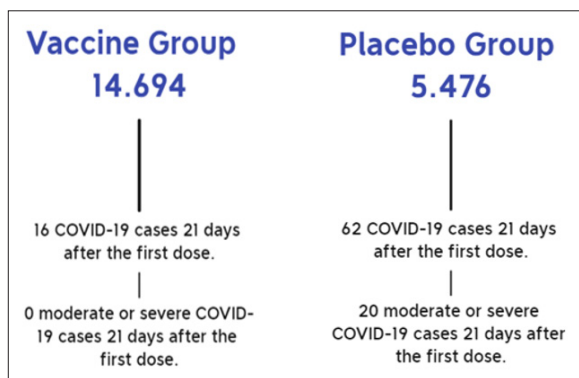


Figure 2: Results of phase 3 studies of Sputnik V
Source: Own Authorship

The main concern of several health agencies around the world is the possibility that the replication of adenoviruses contained in the vaccine can cause infection in some patients. Failure in the way adverse effects were reported. The effectiveness rate may have been lower than described for lack of testing. Another interference in the vaccine's efficacy is the possibility that vaccinated individuals have acquired immunity to the adenoviruses used as vaccine vectors, considering that these are viruses that cause common colds [2,5].

The WHO, as well as the European Medicines Agency (EMA), have not yet approved the Sputnik V vaccine. Among the concerns are the problems related to cross-contamination and sterility, which are part of the quality control of the immunizing agent. Another important point is the fact that Russia itself has immunized only an eighth of its population, which is a lower number when compared to western countries [6].

The low number of countries that imported the vaccine must be considered as a factor that demonstrates that the problems related to the effectiveness of Sputnik V go beyond political interests. Only in the long term will it be possible to establish whether the Russian vaccine is safe and effective. Finally, current evidence raises pertinent doubts regarding the immunization of both governments and the population, which will certainly lead to the choice of vaccines other than Sputnik V.

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