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Safety and efficacy of the Russian COVID-19 vaccine: more information needed

We read with great interest the results presented by Denis Logunov and colleagues on the safety and efficacy of a Russian vaccine for COVID-19.[1]

Although the study results are potentially significant, we have several concerns, which, due to the accelerated distribution of the vaccine to the population, we described in an open letter signed by us and by several other colleagues who share our concerns.

In particular, after finding multiple repeated patterns in the data, we realised that the numerical values for each studied individual are missing. Such detailed information is needed to understand if different groups or individuals show identical or very similar patterns of data and to understand, in a group with identical or very similar percentages of CD4+ and CD8+ T cells at time 0, the degree of overlap of these two independent, continuous variables.

As for comparing post-vaccination immunity with antibody response to infection with severe acute respiratory syndrome coronavirus 2, it is unclear how many of the 4187 individuals from Moscow who had recovered from COVID-19 were included in the analysis of receptor binding domain-specific and neutralising antibodies,[1] and how they match to the experimental cohorts regarding, for example, time after vaccination and natural infection, respectively.

We also believe the individual raw FACS data used for figure 3 are needed to verify the actual overlap of CD4+ and CD8+ T cell proliferation percentages that are apparent from the presented graphs.

We note the statement "Between June 18 and Aug 3, 2020, we enrolled 76 participants to the two studies (38 in each study)".[1] However, according to the published protocols for these two clinical trials (NCT04437875 and NCT04436471), the primary completion date of both studies was Aug 3, 2020; the enrolment should have been completed well before Aug 3, 2020, to have antibody data for all participants at 42 days. In the protocol for NCT04437875, we also noted the statement "Throughout the inpatient observation and the follow-up period (180 days) of visits during the entire study, safety information will be collected." This implies that the entire study was not completed when the Article was published by *The Lancet*, and safety data were partial.

It is also not clear whether the study is a phase 1/2, with a phase 2 starting "no earlier than 5 days"[1] after the phase 1, as reported in the Article, or a two-stage phase 1 study, as per the published protocols.

We feel that a detailed answer and rendering the actual data available would considerably strengthen the significance of the study findings.

EB is the owner of Resis Srl. All other authors declare no competing interests.

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1 Logunov DY, Dolzhikova I V, Zubkova O V, et al. Safety and immunogenicity of an rAd26 and rAd5 vector-based heterologous prime-boost COVID-19 vaccine in two formulations: two open, non-randomised phase 1/2 studies from Russia. *Lancet* 2020; published online Sept 4. https://doi.org/10.1016/S0140-6736(20)31866-3.

Published **Online** September 18, 2020 https://doi.org/10.1016/S0140-6736(20)31960-7

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