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Covid Vaccine: Pfizer, BioNTech and the beginning of the end?

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In a press release on November 9, Pfizer gave a first taste of the results of the Phase 3 study of the Covid vaccine, which was jointly developed with German biotech company BioNTech. With an estimated efficacy of 90% and the start of the vaccination campaign possibly as early as January 2021, there is light at the end of the tunnel. But some hurdles still remain.

How is the vaccine efficacy determined?

All currently ongoing Phase 3 studies for Covid vaccines follow the same procedure. The study participants (approx. 45000) are blindly divided into a placebo and a treatment group. Neither the participants nor the scientists know who is in which group. The participants follow their normal daily routine and report to the study centers in case of side effects and in case of a proven Covid infection. If enough Covid infections are detected, an interim analysis (IA) is performed to determine how many of the patients were in the treatment group. In the course of the IA after 94 cases, Pfizer could now determine an efficacy of 90%, which indicates that at least 85 of the patients were in the placebo group and a maximum of 9 in the treatment group – a remarkable success.

How quickly can the vaccine be distributed?

Both the USA and the EU have already ordered the vaccine from Pfizer. Pfizer expects to produce 50 million doses by 2020 and 1.3 billion doses by 2021. It is a two-dose vaccine, so by the end of 2021, about 600 million people can be vaccinated – a little less than the populations of the EU and the U.S. but probably enough to stop the pandemic at least there. Taking the swine flu pandemic as a scenario, it seems quite possible that 5-10% of the population in western countries could be immunized every month. However, two challenges remain: Pfizer's vaccine has to be stored and transported at -70°C, which requires the establishment of centralized vaccination centers with appropriate equipment. In addition, immunity only sets in 7 days after the last vaccine dose, which is administered 28 days after the first dose. Thus, more than a month passes between the first injection and immunity. The vaccine must also be tested and approved separately for children.

What can still go wrong now?

Even though the level of suffering in society and the economy is currently very high, the child should not be thrown out with the bath water. Due to the long time between injection of the first dose and immunity, it would probably be unwise to start the vaccination campaign before the family reunions at Christmas, as there is a risk of lulling the vaccinated into a false sense of security. However, since medical staff, security forces (police, emergency services, etc.) and residents of hospitals and nursing homes are vaccinated first anyway, this risk is not too high. Nevertheless, social distancing measures will characterize most of 2021. Less risk awareness, the prospect of a vaccine and the already prevailing pandemic fatigue could lead to an increase in the number of cases and ultimately to additional lockdowns.

Do mutations threaten the effectiveness of the vaccine?

The mutated virus variant recently transmitted from minks to humans in Denmark shows 5 mutations in the spike protein on the virus envelope, which is crucial for the vaccines, but there is no reason for concern about this yet. On the one hand, the outbreak of this variant is still limited to a small region in the north of Denmark, and even if it spreads more widely, in the worst case scenario only a reduced vaccine effectiveness can be expected at present. Further mutations at the spike protein could indeed lead to a drastically reduced effectiveness, but even in this case the platform developed by BioNTech can be adapted for future variants of the virus and approved more quickly (similar to the influenza vaccine). With all the excitement about a possible end to the pandemic, the groundbreaking development of the world's first human mRNA vaccine should not be overlooked. BioNTech has not only ushered in a new era of vaccine development, but these developments are also likely to bear fruit in the field of cancer research.

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