

To the employees of the Leibniz-HKI

Questions about COVID 19 vaccination

Dear colleagues,

It is expected that the COVID-19 vaccine from the manufacturers BioNTech / Pfizer with the designation BNT162b2 will also be approved in the European Union in the near future. The vaccine has already been produced in stock and the first vaccinations will probably also be carried out in Germany this year. The data on the efficacy study were published on 10.12.2020, and on 17.12. the Standing Commission on Vaccination (STIKO) at the Robert Koch Institute published its recommendations¹. On this basis, I would like to briefly answer the most important questions about the vaccine BNT162b2 here at the request of the Leibniz-HKI Board of Directors:

1. What is special about the new COVID-19 vaccine BNT162b2?

Unlike all vaccines against infectious diseases available so far, the new vaccine does not contain any proteins, but only so-called mRNA.

An mRNA is the blueprint for a protein. Every cell in our body constantly produces mRNA in large quantities and in great variety in order to be able to produce its protein building blocks. An important disease mechanism of many viruses, including SARS-CoV-2, is that they introduce their viral mRNA into the human cell and thus cause the formation of proteins foreign to the body. The vaccine makes use of this mechanism: it does not contain human mRNA but mRNA that codes as a blueprint for a specific protein of the pathogen SARS-CoV-2. This mRNA is encapsulated in small fat particles that can be taken up by human cells. The human cells can then produce the viral protein for a short period of time, enabling the immune system to produce antibodies and immune cells against the viral protein.

¹ Publication of the Phase III study (New Engl J Med, 2020 DOI: 10.1056/NEJMoa2034577) in conjunction with the study protocol of the vaccine trial in the final version (ClinicalTrials.gov NCT04368728), STIKO recommendations on COVID-19 vaccination of 17.12.2020 (see www.rki.de)

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mRNA...

- can be quickly produced industrially in large quantities. That is why (and because with the relatively simply constructed virus it is very clear which viral protein is most important for recognition by the immune system) the vaccine is available so quickly.
- is not very stable - so the vaccine must be stored at very low temperatures. After vaccination, the short shelf life of mRNA is not a problem.
- is chemically fundamentally different from DNA, which makes up the human genome. Therefore, it is impossible by human standards for the mRNA contained in the vaccine to be incorporated into the human genome and thus remain in the body forever - the direct effect of the vaccine is therefore narrowly limited in time, even if the immune protection it induces can last for a long time.

2. What do we know about the effectiveness of the vaccine?

In the vaccine trial, 18,556 people were fully vaccinated with the new vaccine (two doses at three-week intervals), the so-called "vaccination group". Another 18,530 people received a so-called placebo - i.e. an identical injection that did not contain any vaccine (also 2 doses at intervals of three weeks), the so-called "placebo group". Neither the vaccinated people nor the doctors who vaccinated knew which people received vaccine and which only received placebo. All persons in the study were (and continue to be) observed and regularly interviewed / examined. This primarily involved recording who developed clinical signs of COVID-19 disease - these people were then promptly tested.

In the period starting seven days after the second dose, 170 COVID-19 cases occurred in study participants. Of these, 162 were in the placebo group and 8 in the vaccination group. This results in a calculated efficacy of 95.0%. The vaccine thus proved to be very effective.

COVID-19 cases that occurred between the first and second dose were also counted. Here there were 39 cases in the vaccinated group and 82 in the placebo group. This shows that even one dose of the vaccine offers a certain protection. According to the data of the study, this protection begins at the latest about 12 days after the first vaccination. However, the protection achieved by one dose of vaccine is not sufficient (only about 50%).

The number of severe COVID-19 infections was also lower in the vaccination group (1 case) than in the placebo group (9 cases). This suggests that the disease not only occurs much less frequently in vaccinated persons but is also milder if it does occur.

3. What do we know about adverse effects ("side effects") of the new vaccine?

Adverse effects were precisely recorded and documented both in the vaccination group and in the placebo group (cf. 2.).

Overall, adverse effects occurred in 27% of the persons in the vaccination group and only in 12% of the persons in the placebo group. By far the most common adverse effect was transient mild to moderate pain at the injection site (66-83% of participants). Less than 10% of participants experienced redness or swelling at the injection site. The adverse effects of BNT162b2 are thus quite similar to what we know from other vaccines. This also applies to other possible effects such as fever, fatigue, headache, or muscle pain.

Four people in the vaccination group (about 0.02% of the vaccinated people, i.e. 1 in 5000) experienced more severe side effects. These were shoulder injury, lymph vessel swelling, cardiac arrhythmia and numbness in the leg once each. It is unclear what the connection is between vaccination and the occurrence of the adverse effect in these cases.

Participants in the study have also died. According to medical assessment, these deaths had nothing to do with the vaccination - this is also supported by the fact that 2 deaths occurred in the vaccination group and 4 deaths in the placebo group. Given the high number of study participants, it was statistically expected that participants would die in the course of the study.

4. Why should I get vaccinated?

There are two main reasons for vaccination:

Reason 1: I want to protect myself from the disease. This reason is particularly relevant for older people. With increasing age (approximately from 50-60 years), the frequency of severe courses of COVID-19 increases considerably and mortality rises. People with pre-existing conditions such as cardiovascular disease, diabetes, diseases of the respiratory system, liver, kidney, cancer, or factors such as obesity and smoking also have an increased risk of a severe course of the disease according to current knowledge and should protect themselves.

Reason 2: I want to protect others from the disease. Vaccination helps to prevent the spread of the virus. The intention to protect others from disease is especially important for people who have regular contact with risk groups. This applies to people who work in nursing or in hospital, but also to people who have relatives or friends who belong to risk groups.

It is particularly important, since so-called herd immunity can only be achieved if as many people as possible are vaccinated. Herd immunity describes a situation in which the virus can no longer spread in the population because too many people are immune.

5. If I am vaccinated - do I still need spacing, mask and all the other precautions?

Especially at the beginning of the vaccinations, too few people are vaccinated to be able to directly dispense with these measures. However, there is hope that with an increasing number of vaccinated persons, a return to the usual normality will gradually become more likely from around mid-2021. However, the epidemiological situation is so uncertain that no safe predictions can be made here at the present time. If we do not vaccinate, but wait for the disease to spread normally, it will take several years - irrespective of the fact that this will probably overburden our health care system at some point and certainly cause many more deaths - before herd immunity is established.

6. To whom is the vaccine offered and why?

At the beginning of 2021, there will not be enough vaccine available for everyone to get vaccinated right away. Employees of research institutes such as the Leibniz-HKI will not be given special preference in the distribution of the vaccine. Who receives the vaccine first will probably be based on the recommendations of the Standing Commission on Vaccination (STIKO). According to these recommendations, residents of retirement and nursing homes as well as persons aged ≥ 80 years will be given priority to receive an offer of vaccination. Then follow certain employees in medical facilities, nursing staff and other defined groups. The recommendations of the STIKO are freely available on the internet.²

The implementation of vaccinations is the responsibility of the municipalities (cities and districts). At this point in time, there is no exact information on how the vaccinations will be organised in Jena and surrounding districts.

7. Are there any reasons why I should not be vaccinated?

People who have already been infected with SARS-CoV-2 should not be vaccinated initially. The current findings suggest that a passed through infection leaves a certain immunity. However, there is currently no evidence that vaccination after an undetected SARS-CoV-2 infection would lead to increased adverse effects or even be dangerous. Therefore, it is not necessary to be examined before vaccination to see if one has already been infected with SARS-CoV-2.

Vaccination should not be given during pregnancy or while breastfeeding.

As with any vaccination, the BNT162b2 vaccine should not be administered if you are acutely ill (e.g. have a fever).

People with severe allergies (these are people who carry an "adrenaline injection" [auto-injector] with them at all times to prevent allergic shock in an emergency) should not be vaccinated initially due to a lack of data. Everyday allergies, such as hay fever, or the chicken egg protein allergy relevant to the flu vaccination, are not problematic with regard to the BNT162b2 vaccination.

² https://www.rki.de/DE/Content/Infekt/EpidBull/Archiv/2021/Ausgaben/02_21.pdf?__blob=publicationFile

There are currently no data on the tolerability and effectiveness of the vaccine for children under 16 years of age. At the same time, children rarely become severely ill with COVID-19, so children should not be vaccinated initially.

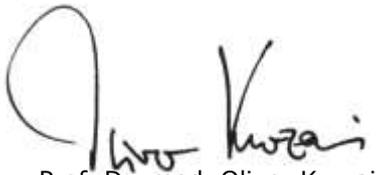
8. Is vaccination compulsory for employees of the HKI?

No. Each employee can decide for themselves. The employer is also not informed about who has been vaccinated or who does not want to be vaccinated.

9. Will you get yourself vaccinated?

Yes. As soon as the vaccine is available and I can be vaccinated, I will get vaccinated because I am convinced that the vaccine is safe and effective.

I hope that these tips clarify any questions. The crisis team is happy to answer further questions via corona@leibniz-hki.de, which will be clarified with doctors as necessary!



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