16 March 2021

FAQ – Temporary suspension of COVID-19 vaccine AstraZeneca

1. Why was vaccination with the COVID-19 vaccine AstraZeneca suspended?

A specific form of severe cerebral venous thrombosis associated with platelet deficiency (thrombocytopenia) and bleeding has been identified in seven cases (as of 15 March 2021) in temporal association with vaccination with COVID-19 Vaccine AstraZeneca.

(1) It is a very serious disease that is also difficult to treat. Of the seven affected individuals, three individuals had died.

(2) The affected individuals had ages ranging from about 20 to 50 years.

(3) Six of the affected persons had a particular form of cerebral venous thrombosis, called sinus vein thrombosis. All six individuals were younger to middle-aged women (see above). Another case with cerebral hemorrhage in platelet deficiency and thrombosis was medically very comparable. All cases occurred between four and 16 days after vaccination with COVID-19 Vaccine AstraZeneca. This presented as a comparable pattern.

(4) The number of these cases after vaccination with COVID-19 AstraZeneca is statistically significantly higher than the number of cerebral venous thromboses that normally occur in the unvaccinated population. For this purpose, an observed-versus-expected analysis was performed, comparing the number of cases expected without vaccination in a 14-day time window with the number of cases reported after approximately 1.6 million AstraZeneca vaccinations in Germany. About one case would have been expected, and seven cases had been reported.

(5) The younger to middle-aged population affected by the severe cerebral venous thrombosis with platelet deficiency is not the population at high risk for a severe or even fatal COVID-19 course.

(6) In addition to the experts from the Paul-Ehrlich-Institut, other experts in thrombosis, haematology, and an adenovirus specialist were consulted with the details of the reported cases. All experts agreed unanimously that a pattern could be discerned here and that a connection between the reported above-mentioned diseases and the vaccination with COVID-19 Vaccine AstraZeneca was not implausible.

After an overall review and consideration of the above facts, the Paul-Ehrlich-Institut recommended that vaccination with the COVID-19 Vaccine AstraZeneca be suspended in Germany as a precautionary measure in

Paul-Ehrlich-Straße 51-59
63225 Langen
Deutschland / Germany

Telefon / Phone +49 (0) 6103 77 0
Fax +49 (0) 6103 77 1234
>> www.pei.de

order to further analyse the cases. The German Federal Ministry of Health (BMG) has followed this recommendation. The Pharmacovigilance Risk Assessment Committee (PRAC) at the European Medicines Agency (EMA) will review during the week of 15 March 2021, whether and how the new findings affect the benefit-risk profile of COVID-19 AstraZeneca and the EU authorisation of the vaccine.

2. How serious are the suspected cases of side effects?

These are suspected cases of very serious side effects. Of the seven people affected, three have died. Whether there is a causal relationship between the vaccination and the disease is currently being investigated.

3. Birth control pills can also cause thrombosis. So why is there all the fuss about the COVID-19 Vaccine AstraZeneca?

It is true that for birth control pills thromboses, even with fatal outcome, are known as a very rare side effect. They are listed in the Summary of Product Characteristics (SmPC). The birth control pill is available only on prescription. Every woman must be informed of this risk by the prescribing physician. For the COVID-19 Vaccine AstraZeneca, there is currently a suspected very rare side effect of sinus vein thrombosis with accompanying platelet deficiency, sometimes fatal. It is not listed in the SmPC.

The consideration of whether the vaccine can continue to be used even though it may cause this very rare side effect (if necessary, after this risk has been added to the SmPC) will be made at the European level by the European Medicines Agency (EMA) and at the national level by politicians. The procedure has been initiated.

4. How many cases in Germany and Europe are affected?

Since vaccinations with the AstraZeneca COVID-19 vaccine began and approximately 1.6 million vaccinations have been performed in Germany to date, seven cases of severe cerebral venous thrombosis (six of them sinus vein thrombosis in women) have been reported in Germany - three affected individuals have died.

5. Who is affected?

Six women and one man aged approximately 20 to 50 years were affected (as of 15 March 2021). The illnesses occurred in the period from four to 16 days after vaccination with COVID-19 Vaccine AstraZeneca.

6. What can I do if I have received a vaccination with the COVID-19 vaccine AstraZeneca?

Based on the suspected cases reported to date, individuals were affected if they continued to feel unwell and had increased headaches during the four- to 16-day period following AstraZeneca COVID-19 vaccination. The cerebral venous thrombosis occurred in seven of 1.6 million vaccinations, according to current knowledge, so it is very rare.

The Paul-Ehrlich-Institut advises that people who have received the AstraZeneca COVID-19 vaccine and feel increasingly unwell more than four days after the vaccination - with severe and persistent headaches or pinpoint bleeding on the skin - should seek medical attention immediately.

7. On Friday, 12 March 2021, the vaccination with COVID-19 Vaccine AstraZeneca has not yet been suspended, but it is now. What has changed since Friday?

On Friday, 12 March 2021, the frequency of cerebral venous thrombosis occurring within vaccinated individuals was within a range that would be expected in the non-vaccinated population. An important tool in pharmacovigilance - drug safety - is to test whether a suspected adverse event occurs more frequently within vaccinated groups of people than in unvaccinated groups (observed vs. expected analysis). If the frequency of an event is within the expected frequency, this is more likely to indicate a coincidental occurrence in temporal relation to vaccination. However, if the observed adverse reaction occurs statistically more frequently in the group of vaccinated individuals, this is a risk signal, i.e., an indication of a possible causal relationship with the vaccination.

On Monday, 15 March 2021, two additional cases of cerebral venous thrombosis were reported after vaccination with COVID-19 Vaccine AstraZeneca. The additional cases on Monday put the number of observed cases well above the expected number. After consulting additional external experts, the Paul-Ehrlich-Institut recommended a temporary suspension of vaccinations with the COVID-19 Vaccine AstraZeneca in the overall view of the available facts on Monday afternoon. This was followed by the German government.

Further Information

- See also FAQ "Why was vaccination with AstraZeneca COVID-19 vaccine suspended?"

8. What should those who have been vaccinated with AstraZeneca's COVID-19 vaccine be aware of?

Anyone who develops persistent headaches or detects skin bleeding four to 16 days after vaccination with COVID-19 Vaccine AstraZeneca, please seek urgent medical attention. However, it is important to note at the same time that this is a very rare potential side effect. It has been reported seven times in Germany in a total of 1.6 million vaccinated individuals. So, it is important to watch out for possible signs of this side effect - at the same time the probability of occurrence is very low.

9. Can those who have only received the initial vaccination with the AstraZeneca vaccine now be vaccinated with a different vaccine?

In principle, it is recommended to establish vaccine protection against COVID-19 by complete vaccination with one vaccine, i.e. two vaccinations with COVID-19 Vaccine AstraZeneca. Although vaccination is currently suspended, it remains to be seen whether the observed cases in the benefit-risk assessment by the European Medicines Agency (EMA) actually result in a permanent suspension of vaccination with the COVID-19 Vaccine AstraZeneca. In addition, there are currently no data available on a combination of different vaccines. Studies on this are currently underway.

For these reasons, vaccine protection should not be completed with another vaccine at this time. In addition, after the initial vaccination, the body has already developed some protection against a severe course of COVID-19. In view of the fact that the vaccination interval between the two vaccinations with AstraZeneca's COVID-19 vaccine should be twelve weeks, and that even exceeding the vaccination interval will not cause the vaccination to become ineffective, the results of the current review should be awaited calmly.

10. When will it be decided whether to continue vaccination with AstraZeneca COVID-19 vaccine?

The experts from the national competent authorities (NCAs) are evaluating the current suspected cases of serious adverse reactions to COVID-19 Vaccine AstraZeneca in the committees of the European Medicines Agency (EMA). Once the scientific investigations are completed, the EMA will make a final assessment of the vaccine's benefit-risk profile and decide whether to continue its marketing authorisation. A first result is expected this week.