

The AstraZeneca vaccine causes rare blood clots. Norwegian researchers are trying to find out why

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Østfold Hospital Kalnes is collecting blood samples from employees who've received the AstraZeneca Vaccine. The goal is to find out whether these individuals also have low levels of platelets, and whether there are traces of the same antibodies as in those who have had the rare adverse reaction. Credit: Gisle Oddstad / VG / NTB

Unusual blood clots should be listed as a very rare side effect of the AstraZeneca COVID vaccine. That was the conclusion by the EU-drug regulator EMA on Wednesday April 7.

This view has been held by Norwegian experts since March 18.

Three previously healthy Norwegians have died, two are still being treated, while one more death is being investigated as possibly linked to the same rare condition. The EMA has only uncovered 222 cases of blood clots that could be connected to the AstraZeneca vaccine, among the roughly 35 million vaccinated in the EU and Great Britain.

"I am glad that the EMA are now realizing there is a connection. There is no other explanation," chief physician and professor at Oslo University Hospital Pål Andre Holme said to Norwegian newspaper Dagbladet.

"I think they've used quite a bit of time to establish the connection that we saw three and a half weeks ago. But of course—there are many conflicts of interest here, and many consequences," he said.

The results of the Norwegian study on the rare condition were recently published in the *New England Journal of Medicine*.

"We have to establish why these particular individuals have become so ill, when others get no [side effects](#) at all," Holme said to TV2.

"That is the big question now."

Comprehensive health studies

And that is exactly what the Norwegian Institute of Public Health is trying to do.

Norway is known for its excellent health registers, as well as a number of large and comprehensive health studies. The NIPH have sent out questions to thousands of participants from two of these studies, [the Norwegian Mother, Father and Child Cohort Study](#) and [the Norwegian Influenza Study](#).

The researchers hope to learn more about the occurrence of this rare side effect in those who have received the AstraZeneca-vaccine compared to those who are not vaccinated. They also hope to find information about whether it can be connected to underlying causes such as gender, age or other diseases and preexisting conditions.

Around 4000-5000 of the more than 100 000 individuals included in the study have received the AstraZeneca vaccine, and a corresponding number have received the Pfizer vaccine, Per Magnus from the NIPH says to Norwegian newspaper VG.

Questions related to the [adverse side effects](#) will be seen in relation to background data from previous questionnaires. Participants may also be called in to give blood samples.

A preprint based on this ongoing study has been submitted to Medrxiv to be published shortly.

Blood samples from vaccinated health workers

A study is also being done at Østfold Hospital Kalnes. Blood samples from employees who have received the AstraZeneca vaccine have been analyzed. The goal is to find out whether these individuals also have low levels of platelets, and whether there are traces of the same antibodies as in those who have had the rare adverse reaction.

[When the study was written about on March 26 by VG](#), the researchers

had yet to find anything abnormal in the blood samples analyzed thus far. More results are expected about a week or two down the line.

The researchers however don't expect to find anything out of the ordinary.

"I think there are a few unlucky individuals who have a reaction and whose bodies create these antibodies, and then I think the rest of us just experience the normal side effects," says Eirik Tjønnfjord, chief physician at the thrombosis clinic at Kalnes to VG.

An important step forward

Gunnveig Grødeland is a senior researcher at the University of Oslo and group leader of the research group Influenza and Adaptive Immunity.

She has been working on a possible universal COVID vaccine since March last year and is considered one of Norway's foremost experts on the topic.

Grødeland welcomes the move from the EMA in including the rare blood clots as a rare side effect of the AstraZeneca vaccine.

"It's good that we can now move on from that," she says to ScienceNorway.no.

"We still don't know why these rare and serious side effects occur, but it's an important step forward that we now have data that show a connection between the vaccine and this rare side effect," she says.

Viral vectors make powerful vaccines

Grødeland explains that it may be easier to predict side effects from the mRNA-vaccines from Moderna and Pfizer.

"As they only contain one specific part of the virus embedded in a lipid particle, it's potentially easier to know what the triggered immune response is directed toward. This makes it less likely that this would be an immune response which reacts to natural processes in the body," she says.

The AstraZenca vaccine on the other hand is a so-called adenovirus vaccine, meaning it uses a viral vector to deliver the vaccine in the body.

"This vaccine also contains only a specific part of the virus, however the viral vector delivering this chosen part of the virus may also be recognized by the immune system as foreign. As such, we will develop immune responses both to the [coronavirus](#) part and the delivery part. However, the presence of the viral delivery vector also makes the vaccine very powerful," Grødeland explains.

"The AstraZeneca vaccine thus may activate the breadth of the immune system and the creation of both antibodies and T-cells. Both of these give protection, but it is possible that such a powerful activation of the immune response also increases the risk of unforeseen side effects," she says.

Four possible theories

Grødeland has previously suggested four different reasons for why the rare side effects have occurred, to Norwegian national newspaper Dagbladet:

- The chemical formulation in the AstraZeneca vaccine
- The adenovirus technology, which is common for AstraZeneca,

Johnson & Johnson and Sputnik

- The spike protein from the COVID vaccine, which all the vaccines contain
- Specific characteristics which give some individuals a very rare and adverse reaction to one of the three factors listed above

Grødeland doesn't think the explanation lies in the chemical formulation of the AstraZeneca vaccine.

"At least not if we are talking about this particular and very powerful [immune response](#). I don't see what in the formulation which could give such a response," she says to Dagbladet.

She also doesn't believe it's the spike protein—as that should mean that we would see similar responses from the mRNA vaccines, which we have not so far.

It is possible that the triggering cause is within the individuals who have the reactions.

"The explanation could be connected to the vaccine, or not. And if it is connected to the vaccine, it could be one of the three first points, or factors within the individuals which give them rare reactions to one of the three points. So this is complicated," Grødeland says.

It will take time

The news of possible blood clot side effects from the Johnson & Johnson vaccine strengthens the theory that the reaction may be connected to the adenoviral vector, Grødeland says to sciencenorway.no.

"But we still don't know why it happens," she stresses.

She believes we will eventually find the triggering factor behind these rare and adverse side effects but cautions that it will take time. Hopefully months, not years.

Neither gender nor age can be used to exclude at risk groups, according to Grødeland.

"More women than men have had this rare side effect. But the number of men is too high to allow us to exclude this group from risk. And although the EMA were clear that this is appearing more often in young people, it has also been observed in some older individuals. So it's difficult to use age in order to find a group that can be given this [vaccine](#) without there being any risk of the rare side effect," she says.

More information: Nina H. Schultz et al. Thrombosis and Thrombocytopenia after ChAdOx1 nCoV-19 Vaccination, *New England Journal of Medicine* (2021). [DOI: 10.1056/NEJMoa2104882](https://doi.org/10.1056/NEJMoa2104882)

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