

Significantly more mild bleeding episodes with AstraZeneca vaccine than mRNA vaccines

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An unpublished preprint of a study done by the Norwegian Institute of Public Health, NIPH, concludes that the AstraZeneca COVID-vaccine may lead to less severe bleeding disorders, and not only the very rare blood clotting side effects that have been widely reported.

The researchers used an [ongoing study](#) called the Norwegian Mother, Father and Child Cohort Study to examine questions related to side effects observed in people who have received the AstraZeneca [vaccine](#) in various European countries.

Participants were asked through electronic questionnaires about potential side effects after COVID-19 vaccinations such as skin bleeding, nose bleeds and bleedings in the gum (gingival bleeding). This was linked with the type of vaccine they had received.

Significantly more cases of bleeding

The risk of bleeding was 20 times higher among people vaccinated with a adenovector-vaccine, like AstraZeneca, compared to those who had received an mRNA-vaccine.

Only four out of the nearly 2900 participants who had received an mRNA vaccine, like the ones produced by Moderna and Pfizer, reported skin bleeding as a side effect. This equals 0.1%.

124 of nearly 4500 who had received the AstraZeneca vaccine reported the same—amounting to 2.8%.

The differences were also stark for nose bleeds and gum bleeds:

- Nose bleeds—Adenovector: 2.0%, mRNA vaccine: 0.3%
- Gum bleeds—Adenovector vaccine: 1.6%, mRNA vaccine: 0.2%

"In this study, cohort participants vaccinated with the adenovirus-vectored vaccine reported bleeding episodes significantly more frequent as compared to recipients of mRNA vaccines," the researchers write.

The only other variable that showed a clear association to bleeding

episodes, besides the different vaccines, was gender. 3.1% of women reported skin bleeding as opposed to 1.3% men.

The study will soon be available as a preprint on Medrxiv, according to the lead author, Lill Trogstad. ScienceNorway has read the preprint.

Self-reported side effects

Trogstad from the division of Infection Control and Environmental Health at the NIPH cautions that this is an observational study. The side effects have not been clinically observed, they are self-reported by those who have answered the digital questionnaire.

"We don't yet know what this means. There is a significant difference in reported side effects based on which vaccine the recipients have been given. It's an interesting finding, but we cannot yet know the mechanisms behind these observations," she says to sciencenorway.no.

"However, one might speculate that the adeno-vectored vaccine may increase risk of minor bleedings," she says.

The researchers discuss the possibility of awareness bias, that participants who received the AstraZeneca vaccine might overreport bleedings due to all the attention this has been given in the media lately. Although this cannot be entirely ruled out, "it is unlikely to explain the large differences in reported bleeding episodes reported in the current study, they write.

Need to analyze blood samples

Whether or not these less severe bleedings are related to the rare and serious blood clotting events, cannot be determined without further

investigation.

"We have not yet analyzed blood samples from these participants, and until we do that we won't know if this is related to the rare side effects otherwise observed related to the vaccine," Trogstad says.

The study will be followed by an analysis of blood samples, she reports.

"We have [blood samples](#) from many of these participants from throughout the pandemic, and we just started a new round of collections. So we have samples from before and after the vaccination that we can include," she says.

Most likely caused by adenoviral vector

"This is an important observation, and underscores the connection between the AstraZeneca vaccine and the rare and serious side effects of blood clots that we have seen so far," says Gunnveig Grødeland, senior researcher at the University of Oslo and group leader of the research group Influenza and Adaptive Immunity. She has not been involved with the study.

"Looking at these observations in relation to the cases that are coming out of the U.S. from the Johnson & Johnson vaccine, it is starting to become clear that these side effects most likely are caused by characteristics from the adenoviral vector used to deliver the vaccine," she says.

The AstraZeneca vaccine uses a chimpanzee virus while Johnson & Johnson use a human virus.

"Regardless of whether it is human or from an animal then, it becomes apparent that it is the adenovirus which gives the side effects."

Not a conventional vaccine technology

Grødeland believes this calls for a cautious approach to using adenoviral vectors in vaccines.

"I don't know where it comes from, but somehow there is a misconception out there that this is a well-known tried and tested technology. But that is wrong," she says.

The format is used in the Ebola vaccine, which has been considered a success. But other than that, this is not a conventional method, the researcher explains.

"It has been used experimentally for more than 20 years, there are plenty of studies. But it has not been used in a vaccine which has been rolled out to the masses," Grødeland says.

A late stage clinical trial will typically involve between 10,000–20,000 vaccinated people and a similar number of non-vaccinated people as a control group. The serious blood clotting side effect is very rare, and so it is not odd that they have not occurred in these studies, according to Grødeland.

"In Norway, where we have had a high prevalence, there is about one case per 20,000. So it goes without saying that this is difficult to catch in a clinical study."

The bleedings in the unpublished NIPH-study are mild—nose bleeds and gum bleeds are not so serious.

"A higher prevalence of these kinds of bleedings may be something we have to tolerate. However, what they show us is that there seems to be something about the adenoviral format which is causing this. Which

again means that we can assume that we will not see the same effect from the Pfizer or Moderna vaccines—or vaccines based on other formats," Grødeland says.

Gender is not the answer

The fact that more women than men report the side effects is a well-known phenomenon—women tend to form stronger immune responses from vaccines.

"Just because there is an overweight of women who experience these [side effects](#) doesn't mean we can count men out—there are also cases with men experiencing this. So we can't just say that now we give this vaccine to men while women get something else. I'm afraid it's not that simple."

More information: The prevalence of bleeding episodes after vaccination against COVID-19. Preprint soon to be published in *Medrxiv*

Provided by ScienceNordic

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