



Rare cases of unusual blood clots, low platelets and hemorrhage following use of COVID-19 Vaccine AstraZeneca

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Week 10/2021

7. March

- Austria suspends batch of AZ vaccine following two reports of coagulation disorder and blood clots

11. March

- Denmark pauses use of AZ vaccine due to one “blood-clot-death” in DK
- The Norwegian Institute of Public Health pauses use of the AZ vaccine in Norway – based on the cases in Austria and DK.
- NOMA becomes aware of one death in Norway (cerebral hemorrhage, low platelets)

The following days

Five patients admitted to Oslo University Hospital (4 with cerebral venous sinus thrombosis + thrombocytopenia + cerebral hemorrhage, 1 patient with portal vein thrombosis + thrombocytopenia). Young health care workers.

13. March

NOMA and The Norwegian Institute of Public Health held a press conference. Message:

- Serious cases among young health care workers 3-14 days after first dose of AZ Vaccine.
- Advised that people who received the vaccine should seek medical assistance immediately if they developed symptoms consistent with this rare and serious combination of blood clots and low blood platelets.



18. March

Professor Pål Andre Holme at Oslo University Hospital claims that the mechanism behind the rare disease has been found:

- *In collaboration with the section for advanced platelet immunology at University Hospital of Northern Norway, we have now detected specific antibodies against platelets (PF4) that can give such an image.*



- This theory was later confirmed by professor Greinacher, Greifswald University Hospital / Paul-Ehrlich-Institute



Rare cases of unusual blood clots with low blood platelets following use of AZ vaccine

- Typical picture
 - Blood clots in veins in the brain (cerebral venous sinus thrombosis) or the abdomen (splanchnic vein thrombosis) and in arteries.
 - Low levels of blood platelets (thrombocytopenia)
 - Sometimes bleeding
- Plausible mechanism
 - An immune response. Antibodies against platelet factor 4 (PF4)
 - A condition similar to heparin induced thrombocytopenia, HIT.
 - So far no specific risk factors have been confirmed.
- Treatment is difficult

7th April

- EMA's safety committee (PRAC) concluded that unusual blood clots with low blood platelets should be listed as very rare side effects of Vaxzevria (COVID-19 Vaccine AZ).
 - Conclusion based on review of 62 cases of cerebral venous sinus thrombosis (CVST) and 24 cases of splanchnic vein thrombosis reported in the EU drug safety database as of 22 March. 18 were fatal.
 - As of 4 April 2021 169 cases of CVST and 53 cases of splanchnic vein thrombosis were reported to EudraVigilance. 34 million people had been vaccinated in the EEA and UK by this date.
- No specific risk factors have been confirmed.
- How often does this occur? 1:100 000 (?)

7th April - Benefit / risk

- EMA confirms overall benefit-risk remains positive
- National authorities must decide which vaccines to use in their vaccination program, based on
 - The burden of Covid-19
 - Access to other vaccines
 - Capacity in the health care system
- In Norway:
 - 10 persons under the age of 50 have died as a result of Covid-19
 - 5 serious cases (3 deaths) following 130 000 doses of AZ (mainly young health care workers)

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