

Overview adverse events COVID19 M&E meeting – 24/3/2021

Thrombosis and thrombocytopenia after AstraZeneca vaccination:

Researchers at the University of Greifswald in Germany have most likely found a solution for patients who develop the extremely rare combination of thrombosis and a sudden shortage of platelets (thrombocytopenia) after vaccination with the AstraZeneca vaccine. The mechanism causing this complication seems to be similar to Heparin-Induced Thrombocytopenia (HIT). When a patient develops HIT, the heparin causes an overreaction of the immune system. The platelets will be used at a rapid rate, resulting in a deficiency. In addition, the platelets also cause blood clots in the brain. The AstraZeneca vaccine may probably induces antibody formation against platelet antigens in analogy to HIT, i.e. HIT mimicry. These antibodies appeared 4–16 days after vaccination. Patients with this very rare complication after vaccination (about 1:1.000.000) should be treated with an anticoagulant other than heparin.

Lareb received 4 reports of cases with possibly a combination of thrombosis and thrombocytopenia. External experts will look into these cases.

Pulmonary embolism

In a first, rough analysis of Lareb, the number of reports of pulmonary embolism with the AstraZeneca vaccine seems to be higher than would be expected based on background incidence. For the other thromboembolic events and the other vaccines, the O / E is not > 1, but the extent of underreporting is not known, so it cannot be ruled out.

Deaths

In the first 8 weeks of the Dutch COVID-19 vaccination campaign, 94 reports with a fatal outcome were received by Lareb. All cases were 65+ years of age. The cases presented a large variety of disease courses, events before and after vaccination, and causes of death. In the large majority of cases, vulnerable and often already progressively deteriorating health states and/or recent development of potentially fatal conditions unrelated to the vaccine, seem to be the most logical explanations for the cause of the events. They do not seem to point towards any unusual causes of death in this age range. At this moment in time, Lareb does not see any patterns that point towards serious adverse events leading to fatal outcome.

In some of the deceased reported, the vaccination caused reactogenicity related adverse events that led to a clear bend in their health state. These adverse events, such as fever, nausea, malaise are in themselves not causes of death, but may have contributed to deterioration of an already vulnerable health state or condition.

Hyperpyrexia

Hyperpyrexia is more frequently reported with AZ than with Pfizer and Moderna (90, 49 and 14 times). This may be related to a younger average age of the people vaccinated with AZ. For AZ the mean and median age was 36 and 32 years, for Pfizer 41 and 40 years, and for Moderna 48 and 46 years.