

Overview adverse events COVID19 M&E meeting – 31/3/2021

Lareb

Thrombo-embolic events:

The Observed / Expected analysis for DVT, pulmonary embolism and ischemic stroke shows that the number of reports per vaccine is generally lower than the background incidence, although the extent of under-reporting is unknown. For pulmonary embolism after AstraZeneca, the number of reports was calculated to be very close to the background incidence. This is a possible signal that the risk of thrombosis may be increased with this vaccine. This cannot be further quantified on the basis of spontaneous reports, additional epidemiological research is needed for this.

Thrombocytopenia and/or haemorrhage

Until 18-03-2021, Lareb received 129 reports of COVID-19 vaccines related to haemorrhage or thrombocytopenia. These occur with all vaccines, but the frequency appears to be higher after AstraZeneca; possibly stimulated due to media attention or because of the relatively high number of reports after AstraZeneca due to high reactogenicity. Due to the heterogeneity of the reported responses, no comparison with background incidence has (yet) been made. The mentioned haemorrhage is mainly in the skin and nosebleeds with a relatively short latency period (mostly <3 days). Serious reports were thrombocytopenia, cerebral haemorrhage and gastrointestinal bleeding. There have been 8 reports with deaths as outcome (cerebral haemorrhage, gastrointestinal haemorrhage, lung haemorrhage).

EMA

Last week, EMA's safety committee, PRAC, confirmed that the vaccine is not associated with an increase in the overall risk of blood clots and that the benefits of the vaccine in combating the still widespread threat of COVID-19 continue to outweigh the risk of side effects. The committee recommended including more information and advice for healthcare professionals and the public in the vaccine's product information. The MEB reports that this recommendation will be adopted.

PRAC is continuing its assessment of the reported cases. An expert meeting on 29 March provided additional input into the assessment on aspects such as any plausible mechanism of action, possible underlying risk factors and any additional data needed to gain a deeper understanding of the observed events and the potential risk. The outcome of this expert meeting, together with further analysis of the reported cases, will feed an updated recommendation which is expected next week.