On the occasion of the start of vaccinations with AstraZeneca's COVID-19 vaccine, the Paul-Ehrlich-Institut summarises important facts about the safety and efficacy of the vaccine in an information sheet. The Paul-Ehrlich-Institut currently provides information on its assessment of suspected case reports and other results of adverse event monitoring (pharmacovigilance) at bi-weekly intervals on its website.

Summary

"AstraZeneca's COVID-19 vaccine is highly effective. It prevents COVID-19 disease in the majority of cases or alleviates symptoms when disease occurs. None of the study participants vaccinated twice in the pivotal trials required hospitalisation with coronavirus 2 infection following AstraZeneca vaccination. Vaccine reactions occur relatively frequently after administration of the vaccine. But they are short-lived and usually reflect the body's normal immune response to vaccinations. Each individual vaccinated benefits from the expected protective effect."

Efficacy

The efficacy of the AstraZeneca COVID-19 vaccine is described as 60% in the European Medicines Agency (EMA) SmPC. This value represents a conservative estimate based on several studies and evaluations. Depending on the vaccine dose and the interval between the two vaccine doses, higher efficacy values have also been described in other evaluations; among other things, the German Standing Committee on Vaccinations (Ständige Impfkommission, STIKO) and the...
British Medicines Agency MHRA describe an efficacy of 70%. These efficacy data are for the originally circulating SARS coronavirus-2 (CoV-2). The efficacy of a vaccine in the SmPC describes the reduction in the so-called "relative risk" in the group of vaccinated compared to the non-vaccinated with comparable risk of infection, and not the protective effect and efficacy for the individual vaccinated. Thus, an efficacy of 60% does not mean 60% protection of the vaccinated, roughly equivalent to mitigation of disease compared to disease in the unvaccinated, but that 60% of cases are prevented that would otherwise occur without vaccination. In addition, the data presented suggest that not only is disease prevented, but disease severity as well as hospitalisation rates are reduced. In the relevant evaluation of the approved dose regimen, 8 of 154 COVID-19 sufferers in the control group were hospitalised, whereas 0 of 64 COVID-19 sufferers in the vaccinated group were hospitalised. Every single vaccinated person benefits from this expected protective effect in terms of disease severity. This highlights the particular benefit of vaccination in populations such as hospital and nursing home staff who are at ≥risk for SARS Cov-2 infection and subsequent COVID-19 disease.

Safety and Transient Vaccine Reactions

In clinical trials of AstraZeneca COVID-19 vaccine, the most commonly reported vaccine reactions among those vaccinated (≥ 18 years) were tenderness at the injection site (>60%), pain at the injection site, headache, and fatigue (>50%), muscle pain and malaise (>40%), feeling feverish and chills (>30%), joint pain, and nausea (>20%). Frequent (between 1% and 10%), fever >38°C, swelling and redness at the injection site, nausea, and vomiting occurred. Occasionally (between 0.1% and 1%), lymph node swelling, pruritus, or rash were reported. These reactions usually occur shortly after vaccination and are not associated with more severe or prolonged illness. The nature of the adverse reactions usually reflects the body's normal immune response to vaccination. An analysis of pre-approval clinical trial safety data indicated higher systemic reactogenicity of COVID-19 vaccines compared with meningococcal conjugate vaccine MenACWY (Follgatti PM et al, The Lancet 2020, 396, 467 ff). It is known from clinical trials that the reactogenicity of the vaccine is lower in older individuals than in younger individuals (Ramasuany MA et al, The Lancet 2020, 396, 1474 ff) and lower at the second vaccine dose than at first vaccination.
As part of the spontaneous reporting of suspected cases of possible adverse reactions and vaccine complications, the Paul-Ehrlich-Institut was notified of several reports from clinics and nursing services/facilities of increased sickness among personnel vaccinated with the AstraZeneca COVID-19 vaccine. The reported reactions are known and listed in the SPC as systemic, transient adverse reactions such as fever, chills, headache, muscle and limb pain, and general feeling of illness, which overall can be summarised as flu-like symptoms.

As part of its responsibilities, the Paul-Ehrlich-Institut participated in the European evaluation and approval of the COVID-19 vaccines currently available in Germany and recommended for priority vaccination by the STIKO.

The AstraZeneca COVID-19 vaccine is currently used for vaccination of persons under 65 years of age according to prioritization and recommendation of the STIKO. This vaccine is a vector vaccine that can be transported and stored at refrigerator temperatures. The Paul-Ehrlich-Institut provides the technical and usage information on its website (www.pei.de), which provides guidance on the properties of the vaccine.