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Case Report

Deaths associated with newly launched SARS-CoV-2 vaccination (Comirnaty®)

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ABSTRACT

Since 27th December 2020, a mRNA vaccine from BioNTech / Pfizer (Comirnaty®) has been used across Germany. As of 12th March 2021, 286 fatalities of vaccinated German individuals were registered at the Paul-Ehrlich-Institute with time intervals after vaccination between one hour to 40 days. From our catchment area in northern Germany, we have so far become aware of 22 deaths in connection with vaccination in a 5 week period (range: 0–28 days after vaccination). Three death cases after vaccination with Comirnaty®, which were autopsied at the Institute of Legal Medicine Hamburg, are presented in more detail. All three deceased had severe cardiovascular diseases, among other comorbidities, and died in the context of these pre-existing conditions, while one case developed a COVID-19 pneumonia as cause of death. Taking into account the results of the postmortem examination a causal relation between the vaccination and the death was not established in any case. If there are indications of an allergic reaction, histological and postmortem laboratory examinations should be performed subsequent to the autopsy (tryptase, total IgE, CRP, interleukin-6, complement activity C3/C5).

1. Introduction

On 21st December 2020, the mRNA vaccine from BioNTech / Pfizer (Comirnaty®) was approved in the European Union (EU) as the first vaccine against the SARS-CoV-2 virus. Since 27th December 2020 this vaccine has been used nationwide in Germany. As in many other EU countries, highest vaccination priority in Germany is given to nursing home residents, persons older than 80, as well as medical and nursing staff [1]. In Germany, the Paul-Ehrlich-Institute (PEI) is responsible for the approval of vaccines, i.e., the evaluation of quality, efficacy, and drug safety after approval. After a vaccine has been approved, all reports of suspected side effects or vaccine complications, including deaths, are continuously recorded and evaluated. The PEI currently publishes weekly safety reports on suspected complications after vaccination including the number of fatalities registered.

There have been 7,093,082 vaccinations with Comirnaty® in Germany up to 12th March 2021 according to the Robert Koch-Institute (RKI) [2]. As shown in the safety report of the PEI [3] of 23rd March 2021, mainly transient local reactions and general reactions have been observed in adverse reactions reported after vaccination with Comirnaty®, without these being specified in more detail. As of 12th March 2021, 286 vaccinated individuals died in Germany from one hour to 40 days after vaccination. The average age of the deceased was 74 years. In the vast majority of individuals who did not die from COVID-19 infection, there were multiple pre-existing conditions, such as carcinoma, renal failure, and cardiovascular disease, which were assumed to be the cause of death [3]. The report does not provide more detailed information on the causes of death, However, it is not stated how many of these deceased had been autopsied.

According to press reports, Norway had already changed its vaccination indications about 3 weeks after the start of the vaccination period following 23 deaths in temporal connection with a COVID-19 vaccination (BioNTech / Pfizer and Moderna). The deaths had all occurred after initial vaccination of elderly (>75 years) and multimorbid patients [4]. Again, until now no information is available about the autopsy rate of these 23 cases. The Norwegian Office of Public Health (Folkehelseinstituttet) points out that even minor side effects could have serious consequences for seriously ill patients and that the positive effect of vaccination is thus lost. Therefore, a thorough consideration should be made in each individual case by the medical staff [5]. Meanwhile, Norway and Denmark, and temporarily Germany and other countries, have paused administration of AstraZeneca's vaccine because of the apparent clustering of thrombotic complications.

After the start of vaccination in Germany and abroad, anaphylactic

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