

Avian influenza vaccine induced immune responses – study design and methods of a clinical vaccine trial in Finland

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Highly pathogenic avian influenza (HPAI) A(H5N1) clade 2.3.4.4b viruses have circulated widely among European bird populations since 2020. In 2023, mass deaths of wild birds due to HPAI were observed in Finland, followed by spread of infections to farmed fur animals leading to outbreaks on 71 farms. The emergence of infections in mammals, particularly mammal-to-mammal transmission, is a significant concern. Due to a significant increase in cases across Europe in 2023, Finland decided in Q2/2023 to prepare for acquiring vaccines for those at risk. Vaccinations became possible in June 2024, immediately after the H5N8 vaccine (Zoonotic Influenza Vaccine, Seqirus, tailored against clade 2.3.4.4b) received marketing authorization. Vaccination is recommended for those at risk through direct/indirect exposure to infected animals, including fur farm and poultry workers, veterinarians in the public sector, bird ringers, and laboratory personnel handling HPAI samples. The primary objective of the study is to evaluate humoral and cell-mediated immune responses induced against the H5N1 2.3.4.4b clade, and other H5N1 clades identified before or during the study. While the aim was to recruit 300 subjects from the target population, lower-than-expected vaccine acceptance and the 12-month limit of the authorized shelf life may hinder this goal. Samples will be collected before vaccination, 3 weeks after each dose, and 6 and 12 months after the final dose. The data generated in this study will be crucial for evaluating the vaccine-induced immunity and determining the potential level of protection across target populations.