

DANFLU-1: An Innovative Pragmatic Randomised Feasibility Trial of Influenza Vaccines

The relative vaccine effectiveness (rVE) of high-dose quadrivalent influenza vaccines (QIV-HD) versus standard-dose quadrivalent influenza vaccines (QIV-SD) against hospitalisations and mortality in the general older population has not previously been evaluated in an individually randomised trial

There is a need to assess the feasibility of this innovative trial design



STUDY AIM:

To evaluate the feasibility of integrating an individually randomised study of QIV-HD vs QIV-SD into routine seasonal influenza vaccination practice using administrative health registries for data collection



KEY METHODS:

This was a pragmatic, open-label, active-controlled, randomised feasibility trial in Danish citizens aged 65 to 79 years during the 2021–2022 influenza season



Participants were randomly assigned 1:1 to receive QIV-HD or QIV-SD. Randomisation was integrated into routine vaccination practice

RESULTS:

12,477 randomly assigned participants were included in the final analyses

Complete follow-up data were obtained for 99.9% of participants demonstrating the feasibility of registry-based data collection



Overall, there was a **lower incidence of hospitalisation** for influenza or pneumonia and **all-cause mortality** in the QIV-HD group compared with the QIV-SD group

rVE of QIV-HD vs QIV-SD against hospitalisation for influenza or pneumonia of

64.4%

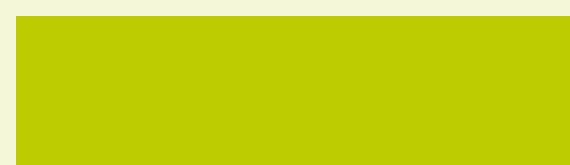
(95% CI, 24.4 to 84.6)



rVE of QIV-HD vs QIV-SD against all-cause mortality was

48.9%

(95% CI, 11.5 to 71.3).



Conducting a pragmatic randomised trial of QIV-HD versus QIV-SD using existing infrastructure and registry-based data collection was feasible

The findings of a lower incidence of hospitalisation for influenza or pneumonia and all-cause mortality with QIV-HD vs QIV-SD require confirmation in a future fully powered trial

To read more go to:

<https://evidence.nejm.org/doi/10.1056/EVIDoa2200206>

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