Global **Influenza** Initiative

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 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

To download a copy of this infographic visit the Nivel FluCov website: Project FluCov • 2021-ongoing | Nivel

Reference: Johansen ND, et al. A Pragmatic Randomized Feasibility Trial of Influenza Vaccines. NEJM Evid 2023;2(2).

CI, confidence interval; QIV-HD, high-dose quadrivalent influenza vaccine; QIV-SD, standard-dose quadrivalent influenza vaccine; rVE, relative vaccine effectiveness