The Invested Trial - High Dose Versus Standard Dose Influenza Vaccine In Patients With High Risk Cardiovascular Disease: Results From The Invested Trial

Purpose: Test the efficacy of high-dose trivalent (HD-IIV3) versus standard-dose quadrivalent influenza vaccine (IIV4) in patients with a history of recent hospitalization for acute myocardial infarction (MI) or heart failure (HF).

Trial Design: •Double-blind RCT. •157 sites in US/Canada •Total n = 5260, •HD-IIV3 n =2630 with 3577 vacc. •IIV4 n=2630 with 3577 vacc. •Post-MI (1 yr.) or HF hospitalization (2 yrs.) with one additional CV risk factor •Participants followed up to four times/yr. for three influenza seasons •>90% power to detect 18% RRR (HR 0.82)

Primary Endpoints: Composite of all-cause mortality or hospitalization for a cardiovascular or pulmonary cause

Secondary Endpoints: Total hospitalizations for CV or pulmonary causes or all-cause death, •Time to first occurrence of death due to CV causes or CV hospitalization, •Time to first occurrence of all-cause death or hospitalization due to CV or pulmonary causes, •Time to first occurrence of individual components of the primary efficacy endpoint

Primary/Secondary Endpoints	High Dose (n = 2630, 3577 vacc.)	Standard Dose (n = 2630, 3577 vacc)	Hazard/Mean Ratio (C.I.)	P value
First CP hosp. or all-cause death	975	924	1.06	1.21
Year 1				
Year 2	91	84	1.08	0.61
Year 3	431	377	.13	0.10
CV death/hosp within each season	471	463	1.01	0.86
	805	752	1.08	0.16
•1st CP Hosp or death	955	918	1.06	0.24
•All-cause death	223	222	1.01	0.96
• Tot CP hosp/death	1857	1784	1.04	0.44
•Influenza Hosp.	10	8		
•Pneumonia Hosp.	47	41		

Results: HD-IIV3 did not reduce all-cause death or hospitalizations for cardiac or pulmonary causes compared with SD-IIV4.

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