

The effect of influenza vaccination in HIV-infected persons

CITATION

Tasker SA, Treanor JJ, Paxton WB, Wallace MR. Efficacy of Influenza Vaccination in HIV-Infected Persons: a randomised double-blind placebo-controlled trial. *Ann Intern Med* 1999;131:430-3

RESEARCH QUESTION

What is the effect of influenza vaccination in HIV-infected persons?

THE STUDY DESIGN

Randomised, double-blind, placebo-controlled trial

STUDY SETTING

Hospital-based outpatient US military clinic; during one influenza season (enrolment between October and December 1995 follow up during fall and winter 1995-1996)
Informed consent and ethics approval obtained

PARTICIPANTS

Included: HIV positive persons who have not yet received their annual influenza vaccination

Excluded: Those who already received vaccination

INTERVENTIONS

Influenza vaccine (whole virion containing 15ug each of A/Johannesburg/33/94 [H3N2], A/Texas/36/91 [H1N1] and B/Harbin/07/94 [Pasteur Merieux Connaught, Lyon, France]) vs. placebo

OUTCOMES

Influenza antibody titres

CD4 cell counts and Plasma HIV-1 RNA levels

Viral cultures and respiratory illness

Did not specify which were primary or secondary outcomes. Measured at baseline, 1 and 3 months after vaccination. Viral cultures were taken from those with respiratory illness and all participants were interviewed about respiratory illness (defined as any rhinitis, pharyngitis or cough) experienced during the study period.

RISK OF BIAS (Risk Scale: Low – Moderate – High)

SELECTION BIAS: Low - Moderate

Computer generated random sequence was used. It was kept sealed until end of study. Do not describe how allocation was concealed. Baseline characteristics appears similar however no significance tests and also no standard deviation for age.

PERFORMANCE BIAS: Low

Pharmacy staff prepared syringes that were filled with either saline or with influenza vaccine purchased by hospital for clinical use. Participants and clinic staff were blind seeing that vaccine could not be distinguished from placebo.

DETECTION BIAS: Low - Moderate

Participants blind. Mention that allocation sealed until end of study. Unclear whether investigators and laboratory personnel unaware of allocation. Main outcomes measured using blood tests.

ATTRITION BIAS: Low

Loss to follow-up low.

	Influenza vaccine	Placebo
Started	55	47
Antibody titres	49 (89%)	43 (91%)
Respiratory illness	55 (100%)	47 (100%)

STUDY FINDINGS

Influenza antibody titres

Influenza antigen		Pre vaccine	Post-vaccine	P value	% participants responding*
A/Texas	Vaccine	3.55	4.02	0.045	12
	Placebo	3.83	3.95		5
A/Johannesburg	Vaccine	2.24	3.18	<0.001	29
	Placebo	2.05	2.07		2
B/Harbin	Vaccine	5.36	6.43	0.008	36
	Placebo	4.54	5.00		15

* ≥ 4 fold increase in antibody titre

	Treatment	Event Rate	RRR	ARR	NNT
A/Texas	Vaccine	0.109	-153%	0.066	NS
	Placebo	0.043	(-388%; 81%)	-0.167; 0.035	
A/Johannesburg	Vaccine	0.255	-1114%	0.234	4
	Placebo	0.021	-1697%;-532%	-0.356;-0.112	3;9
B/Harbin	Vaccine	0.327	-155%	0.199	5
	Placebo	0.128	-278%;-33%	-0.356;-0.042	3;24

NS = non significant

CD4 cell counts and plasma HIV-1 RNA levels

No significant differences

Respiratory illness and viral cultures

	Treatment	Event Rate	RRR	ARR	NNT
Respiratory illness	Vaccine	0.291	40%	0.198	5
	Placebo	0.489	(2%; 79%)	0.011; 0.385	3;88
Symptomatic laboratory confirmed influenza A	Vaccine	0	100%	0.213	5
	Placebo	0.213	2%;79%	0.096;0.330	3;10

No patients hospitalised or treated for pneumonia during study period.

There was no adjusted analysis to take account of any differences at baseline.

COMMENTS

Good quality study which found that this particular influenza vaccine was effective in reducing influenza and did not influence viral load or CD4 cell counts amongst HIV persons with mean CD4 cell counts of 400 cells/mm³. Unclear about the effect of anti-retroviral usage and the effect on the outcomes.

Prepared by: Taryn Young
E-mail: taryn.young@mrc.ac.za
Date: 5 February 2006