

Single dose of mRNA-1345 vaccine safe, effective against RSV in seniors

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A single dose of mRNA-1345 vaccine is safe and results in lower incidence of respiratory syncytial virus (RSV)-associated disease in older patients, according to a study published in the Dec. 14 issue of the *New England Journal of Medicine*.

Eleanor Wilson, M.D., from Moderna in Cambridge, Massachusetts, and



colleagues conducted a randomized, phase 2 to 3 trial in which adults aged 60 years of age or older were randomly assigned to receive one dose of mRNA-1345 (50 μ g; 17,793 participants) or placebo (17,748 participants).

Participants were followed for a median of 112 days. The researchers found that vaccine efficacy was 83.7 and 82.4 percent against RSV-associated lower respiratory tract disease with at least two signs or symptoms and against the disease with at least three signs or symptoms, respectively. Vaccine efficacy against RSV-associated acute respiratory disease was 68.4 percent. Protection was seen against RSV subtypes A and B and was mainly consistent across subgroups defined according to age and coexisting conditions. Compared with those in the placebo group , participants in the mRNA-1345 group had a higher incidence of solicited local adverse reactions (58.7 versus 16.2 percent) and of systemic adverse reactions (47.7 versus 32.9 percent); most reactions were mild-to-moderate and transient. Overall, 2.8 percent of each trial group had serious adverse events.

"This phase 2 to 3 efficacy trial showed that a single 50-µg dose of the mRNA-1345 vaccine in adults 60 years of age or older was efficacious against a spectrum of RSV-confirmed respiratory disease," the authors write

The study was funded by Moderna, the manufacturer of the mRNA-1345 vaccine.

More information: Eleanor Wilson et al, Efficacy and Safety of an mRNA-Based RSV PreF Vaccine in Older Adults, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2307079

Amanda C. Cohn et al, Continued Progress in the Development of Safe and Effective RSV Immunizations, *New England Journal of Medicine*



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