Ad26.RSV.preF-RSV preF protein vaccine immunogenic in seniors

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An adenovirus serotype 26 respiratory syncytial virus (RSV) vector

encoding a prefusion F (preF) protein (Ad26.RSV.preF) in combination with RSV preF protein is immunogenic and prevents RSV-mediated lower respiratory tract disease in older adults, according to a study published in the Feb. 16 issue of the *New England Journal of Medicine*.

Ann R. Falsey, M.D., from the University of Rochester School of Medicine in New York, and colleagues conducted a phase 2b, proof-of-concept trial to examine the efficacy, immunogenicity, and safety of Ad26.RSV.preF-RSV preF protein vaccine among adults aged 65 years or older. A total of 5,782 participants were randomly assigned to receive vaccine or placebo in a 1:1 ratio. The primary end point was the first occurrence of RSV-mediated lower respiratory tract disease that met one of three case definitions.

The researchers found that RSV-mediated lower respiratory tract disease meeting case definitions 1, 2, and 3 occurred in six, 10, and 13 and in 30, 40, and 43 vaccine and placebo recipients, respectively. For case definitions 1, 2, and 3, vaccine efficacy was 80.0, 75.0, and 69.8 percent, respectively.

From baseline to day 15 after vaccination, RSV A2 neutralizing antibody titers increased by a factor of 12.1. Compared with the placebo group, the percentages of participants with solicited local and systemic adverse events were higher in the vaccine group (local: 37.9 versus 8.4 percent; systemic: 41.4 versus 16.4 percent); most adverse events were mild to moderate. The frequency of serious adverse events was similar between the groups.

"Vaccine efficacy, immunogenicity, and safety were maintained across subgroups defined according to age and the presence of additional risk factors for severe RSV-mediated disease," the authors write.

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manufactures the Ad26.RSV.preF-RSV preF vaccine.

More information: Ann R. Falsey et al, Efficacy and Safety of an Ad26.RSV.preF–RSV preF Protein Vaccine in Older Adults, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2207566