Study to test pneumococcal vaccine in older adults

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Researchers plan to see if a higher dose of a pneumococcal vaccine will create a stronger immune response in older adults who received an earlier generation vaccine against pneumonia and other pneumococcal diseases.

The study supported by the National Institutes of Health will compare two dosages of a pneumococcal vaccine approved for children ages 6 weeks to 5 years, and adults 50 and older. The trial will enroll up to 882 men and women ages 55 to 74.

The study is funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of NIH. Researchers hope to gain new insights into the immune responses needed to provide protection.

More than 300,000 people in the United States are hospitalized annually for pneumonia, according to the Centers for Disease Control and Prevention. In 2009, pneumonia ranked eighth among the 15 leading causes of death in the United States, with adults 55 and older accounting for the majority (92 percent) of all pneumonia-related deaths that year.

The bacterium Streptococcus pneumoniae can cause a type of pneumonia called pneumococcal pneumonia. S. pneumoniae can infect the upper respiratory tract and spread to the lungs, blood, middle ear or nervous system. Children younger than 5 and adults older than 65 are most susceptible to becoming ill from pneumococcal pneumonia. People who have been infected are susceptible to becoming re-infected.

For the past 30 years, the PPSV23 vaccine (23-valent pneumococcal polysaccharide vaccine), known by the brand name Pneumovax 23, has been the standard protection from invasive pneumococcal disease in adults over 65 years of age. While this vaccine protects against pneumococcal meningitis and bloodstream infections, it is unclear how well it protects against bacterial pneumococcal pneumonia. The newer PCV13 vaccine (13-valent pneumococcal conjugate vaccine), known by the brand name Prevnar 13, protects against bacterial pneumonia and other invasive pneumococcal illnesses in children, but the efficacy and most effective dosage in adults is unknown. Earlier studies suggest that PCV13 may not induce as strong an immune response in older adults who previously received the PPSV23 vaccine within the past 5 years as in those who have not.

Researchers will conduct a Phase IIb randomized clinical trial, involving two groups of adults ages 55 to 74. The first group, 294 participants who have never been vaccinated with the PPSV23 vaccine, will receive a single 0.5 milliliter (mL) injection of the PCV13 vaccine. The second group, 588 participants who were vaccinated with the PPSV23 vaccine three to seven years before study enrollment, will be randomized to receive one 0.5 mL injection of the PCV13 vaccine or 1.0 mL of the PCV13 vaccine administered as two 0.5 mL injections, one in each arm. Researchers will evaluate participants' immune responses via blood samples drawn 28 days and 180 days post-injection, to compare responses between those who had previously been vaccinated with the PPSV23 vaccine and those who had not been. The researchers will also evaluate whether the larger, 1.0 mL, dose of PCV13 is more immunogenic than the 0.5 mL dose in participants who were previously vaccinated with the PPSV23 vaccine.

The vaccine study is being conducted at six NIAID-funded Vaccine and Treatment Evaluation Units: University of Iowa, Iowa City; Saint Louis University, St. Louis; Cincinnati Children's Hospital Medical

Center–Infectious Diseases, Cincinnati; Vanderbilt University's Vaccine Research Center in Nashville; Baylor College of Medicine, Houston; and the Group Health Research Institute in Seattle. The study is being led by principal investigator Lisa Jackson, M.D., M.P.H., of the Group Health Research Institute.

More information: Information about the clinical trial is available at ClinicalTrials.gov under the identifier NCT01654263.

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