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Safety of Herpes Zoster Vaccine in the Shingles Prevention Study: a Randomized Trial.

Simberkoff MS, Arbeit RD, Johnson GR, Oxman MN, Boardman KD, Williams HM, Levin MJ, Schmader KE, Gelb LD, Keay S, Neuzil K, Greenberg RN, Griffin MR, Davis LE, Morrison VA, Annunziato PW; Shingles Prevention Study Group.

BACKGROUND: The herpes zoster vaccine is effective in preventing herpes zoster and postherpetic neuralgia in immunocompetent older adults. However, its safety has not been described in depth.
OBJECTIVE: To describe local adverse effects and short- and long-term safety profiles of herpes zoster vaccine in immunocompetent older adults.
DESIGN: Randomized, placebo-controlled trial with enrollment from November 1998 to September 2001 and follow-up through April 2004 (mean, 3.4 years). A Veterans Affairs Coordinating Center generated the permutated block randomization scheme, which was stratified by site and age. Participants and follow-up study personnel were blinded to treatment assignments. (ClinicalTrials.gov registration number: NCT00007501)
SETTING: 22 U.S. academic centers.
PARTICIPANTS: 38 546 immunocompetent adults 60 years or older, including 6616 who participated in an adverse events substudy.
INTERVENTION: Single dose of herpes zoster vaccine or placebo.
MEASUREMENTS: Serious adverse events and rashes in all participants and inoculation-site events in substudy participants during the first 42 days after inoculation. Thereafter, vaccination-related serious adverse events and deaths were monitored in all participants, and hospitalizations were monitored in substudy participants.
RESULTS: After inoculation, 255 (1.4%) vaccine recipients and 254 (1.4%) placebo recipients reported serious adverse events. Local inoculation-site side effects were reported by 1604 (48%) vaccine recipients and 539 (16%) placebo recipients in the substudy. A total of 977 (56.6%) of the vaccine recipients reporting local side effects were aged 60 to 69 years, and 627 (39.2%) were older than 70 years. After inoculation, herpes zoster occurred in 7 vaccine recipients versus 24 placebo recipients. Long-term follow-up (mean, 3.39 years) showed that rates of hospitalization or death did not differ between vaccine and placebo recipients.
LIMITATIONS: Participants in the substudy were not randomly selected. Confirmation of reported serious adverse events with medical record data was not always obtained.
CONCLUSION: Herpes zoster vaccine is well tolerated in older, immunocompetent adults.
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