ORIGINAL ARTICLE

A Randomized, Controlled Trial of an Aerosolized Vaccine against Measles

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BACKGROUND

Aerosolized vaccine can be used as a needle-free method of immunization against measles, a disease that remains a major cause of illness and death. Data on the immunogenicity of aerosolized vaccine against measles in children are inconsistent.

Full Text of Background...

METHODS

We conducted an open-label noninferiority trial involving children 9.0 to 11.9 months of age in India who were eligible to receive a first dose of measles vaccine. Children were randomly assigned to receive a single dose of vaccine by means of either aerosol inhalation or a subcutaneous injection. The primary end points were seropositivity for antibodies against measles and adverse events 91 days after vaccination. The noninferiority margin was 5 percentage points.

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RESULTS

A total of 1001 children were assigned to receive aerosolized vaccine, and 1003 children were assigned to receive subcutaneous vaccine; 1956 of all the children (97.6%) were followed to day 91, but outcome data were missing for 331 children because of thawed specimens. In the per-protocol population, data on 1560 of 2004 children (77.8%) could be evaluated. At day 91, a total of 662 of 775 children (85.4%; 95% confidence interval [CI], 82.5 to 88.0) in the aerosol group, as compared with 743 of 785 children (94.6%; 95% CI, 92.7 to 96.1) in the subcutaneous group, were seropositive, a difference of −9.2 percentage points (95% CI, −12.2 to −6.3). Findings were similar in the full-analysis set (673 of 788 children in the aerosol group [85.4%] and 754 of 796 children in the subcutaneous group [94.7%] were seropositive at day 91, a difference of −9.3 percentage points [95% CI, −12.3 to −6.4]) and after multiple imputation of missing results. No serious adverse events were attributable to measles vaccination. Adverse-event profiles were similar in the two groups.

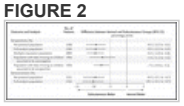
Full Text of Results...

MEDIA IN THIS ARTICLE

FIGURE 1

Eligibility, Randomization, and Follow-up of Children in the Per-Protocol Population.

FIGURE 2



Immunogenicity Outcomes at Day 91 in the Aerosolized and Subcutaneous Vaccine Groups.

ARTICLE ACTIVITY

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CONCLUSIONS

Aerosolized vaccine against measles was immunogenic, but, at the prespecified margin, the aerosolized vaccine was inferior to the subcutaneous vaccine with respect to the rate of seropositivity. (Funded by the Bill and Melinda Gates Foundation; Measles Aerosol Vaccine Project Clinical Trials Registry–India number, CTRI/2009/091/000673.)

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