The Lancet, Volume 384, Issue 9953, Pages 1505 - 1512, 25 October 2014
doi:10.1016/S0140-6736(14)60934-X Cite or Link Using DOI

Published Online: 11 July 2014

Effect of a single inactivated poliovirus vaccine dose on intestinal immunity against poliovirus in children previously given oral vaccine: an open-label, randomised controlled trial

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Summary

Background

Intestinal immunity induced by oral poliovirus vaccine (OPV) is imperfect and wanes with time, permitting transmission of infection by immunised children. Inactivated poliovirus vaccine (IPV) does not induce an intestinal mucosal immune response, but could boost protection in children who are mucosally primed through previous exposure to OPV. We aimed to assess the effect of IPV on intestinal immunity in children previously vaccinated with OPV.

Methods

We did an open-label, randomised controlled trial in children aged 1—4 years from Chinnallapuram, Vellore, India, who were healthy, had not received IPV before, and had had their last dose of OPV at least 6 months before enrolment. Children were randomly assigned (1:1) to receive 0·5 mL IPV intramuscularly (containing 40, 8, and 32 D antigen units for serotypes 1, 2, and 3) or no vaccine. The randomisation sequence was computer generated with a blocked randomisation procedure with block sizes of ten by an independent statistician. The laboratory staff did blinded assessments. The primary outcome was the proportion of children shedding poliovirus 7 days after a challenge dose of serotype 1 and 3 bivalent OPV (bOPV). A second dose of bOPV was given to children in the no vaccine group to assess intestinal immunity resulting from the first dose. A per-protocol analysis was planned for all children who provided a stool sample at 7 days after bOPV challenge. This trial is registered with Clinical Trials