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50% More Intussusception Among Vaccinated: Full Trial Data Is Awaited

According to the [Clinical Trials Registry](#) this study, started in March 2011 was estimated to be complete in April 2014.

The data published in Lancet on March 12, 2014 refers only to the first half of the study (efficacy and safety of ORV 116E assessed in the first year of life). Data on efficacy and safety up to 2 years (from 14 days following the 3rd dose till the age of 2 years (24 months) + up to 14 days.) is still awaited.

Even in this small sample studied for 1 year, the incidence of intussusception among the vaccinated was 50% more than controls. The rush to recommend licensing this drug before presenting the full trial data is surprising.

Furthermore, contrary to expectations, it is now known that transplacental rotavirus IgG interferes with immune response to the live oral rotavirus vaccine (ORV-116E) in Indian infants [Appaiahgari MB, 2014](#). The very low incidence of severe rotavirus gastroenteritis (SRVGE) seen in the study of [Bhandari N, 2014](#) may be due to the protective effect of the transplacental antibodies. The vaccine is probably not needed in these circumstances.

However [Appaiahgari MB, 2014](#) found that higher doses of the vaccine was able to overcome the inhibitory effect of this RV IgG. The safety of the high-dose-vaccine has not been studied and so cannot be recommended as yet.