

- [Efficacy of a monovalent human-bovine \(116E\) rotavirus vaccine in Indian children in the second year of life.](#)

Bhandari N.Vaccine. 2014.[1 comment](#)

[Jacob Puliye](#)2014 Aug 12 01:11 a.m.edited 1 of 1 people found this helpful

I read with interest this paper that describes efficacy and safety of the 116E rotavirus vaccine in the 2nd year of the trial. The results for the first year were published earlier in June 2014 [Bhandari N, 2014](#). The authors need to be congratulated for this study.

However some of the data appears incongruous. According to the clinical trial registry <http://clinicaltrials.gov/show/NCT01305109> one of the secondary outcome measures was to be "safety of ORV 116E for intussusception events [Time Frame: Up to 2 years of age] Safety of ORV 116E for intussusception events in comparison to a placebo will be assessed in all subjects, from day of 1st dose till the age of 2 years (24 months) + up to 14 days". The term used here is 'intussusception events' not specifically only cases with Level 1 certainty.

The multicenter trial was conducted in 3 centers at Delhi, Pune and Vellore. The study was done in 6799 infants of whom 4532 received the 116E rotavirus vaccine and 2267 received placebo. In the Vellore limb of the study 1000 received the vaccine and 500 were given placebo.

[Bhandari N, 2014](#) reports that 8 babies developed intussusception (intussusception by Brighton Level 1 criteria) during the 2 year follow up . However Jehangir et al, in the same issue of the journal Vaccine [Jehangir S, 2014](#) report that there were 16 cases of intussusception (diagnosed on ultrasound) in the 1500 infants followed up at Vellore. 7 of these required radiological reduction meeting Brighton criteria level 1.

It seems unlikely that there were 16 children with intussusception in Vellore center (7 meeting level 1 criteria) and there were only 11 cases in the entire trial. This would mean that there were 7 cases (meeting level 1 criteria) in Vellore among 1500 children studied and only 4 case among the 5041 children at Delhi and Pune. In view of this, I will request the authors to report in the PubMed Commons how many babies in the two group (vaccinated and placebo group) had intussusception (any level of diagnostic certainty by Brighton criteria ) and how many had Level 1, Level 2 and Level 3 certainty.