

Post-marketing Intussusception monitoring in Pakistan after introduction of oral rotavirus vaccine

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Background and objective

Pakistan is the first country in South Asia to introduce vaccine against rotavirus in its routine immunization program through co-financing with GAVI. Monovalent rotavirus vaccine Rotarix[®] was rolled out in 2018 in Pakistan and is given at 6 and 10 weeks of age. Objective of this study is to assess the risk of intussusception (IS) following administration of rotavirus vaccine as part of a routine immunization program.

Methods

Prospective surveillance was established to enrol children <1 year of age. Case patients are enrolled from four major tertiary care hospitals of Sindh and Punjab provinces. A case patient is screened on clinical grounds and confirmed using Level 1 Brighton criteria. Vaccination status of all enrolled case patients is confirmed from vaccination cards and, if required, from vaccination centre records. For all case patients who are less than 8 months of age at the time of enrollment, a follow up is carried out at the age of 8 months to record the vital status and vaccination status of the child.

Results

Enrolment is in progress. Fifty nine confirmed case patients of IS have been enrolled to date. Mean age of enrolled children was 6.1 months and 39 (66%) of enrolled children were male. Out of 52 case patients who had received any vaccines other than birth doses, vaccination record of 43 (86%) case patients was available. Among the enrolled, only two case patients of IS died, rest were discharged home after management.

Conclusion

The study is ongoing and the data will generate important insights about safety of rotavirus vaccine in Pakistan. To determine if an increased risk of intussusception occurs following rotavirus vaccination, a self-controlled case-series analysis using these surveillance data will enable quantification of this risk.