

# **A Randomized Clinical Trial to Evaluate the Immunogenicity and Safety of ROTAVAC<sup>®</sup> in comparison with a licensed rotavirus vaccine in healthy infants**

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## **Background**

- The World Health Organization (WHO) recommends that rotavirus (RV) vaccines should be included in national immunization programs.
- ROTAVAC<sup>®</sup> (nHRV), derived naturally from the human 116E neonatal strain, was licensed in India in 2015 based on promising results of a phase 3, safety and efficacy trial.
- As a pre-requisite for WHO prequalification, we compared the immunogenicity and safety of ROTAVAC<sup>®</sup> to those of a WHO-prequalified, Rotarix<sup>®</sup>.

## **Methods**

- We conducted a multicentre, open-labeled, randomized phase 4 clinical trial where 464 infants, 6 to 8 weeks of age were equally randomized to receive as licensed, the complete regimen of ROTAVAC<sup>®</sup> (3 doses; Group I) or Rotarix<sup>®</sup> (2 doses; Group II).
- Antibody responses (serum anti-RV Immunoglobulin A [IgA]) were measured by enzyme-linked immunosorbent assay (ELISA). The primary analysis was an assessment of non-inferiority of ROTAVAC<sup>®</sup> to Rotarix<sup>®</sup> for geometric mean titer (GMT) for infants who received the complete regimen of either vaccine.

Results:

Conclusions:

Limitations:

Clinical Trials Registration: (CTRI Number: CTRI/2015/12/006428).