Rotavirus Vaccine Interchangeability Trial Begins Enrolling Participants in Kolkata, India

Diarrhoeal disease is one of the most important causes of illness and death among under five years children and Rotavirus is the most common agent causing acute watery diarrhoea in that age group. Rotavirus diarrhoea poses a major public health challenge, especially due to the dehydration caused by acute diarrhoea and vomiting, delayed health seeking behaviours of the caregivers of affected children, and lack of primary healthcare facilities in the vicinity of community settings. In India, it is estimated that 11.37 million episodes of rotavirus gastroenteritis occur every year requiring 3.27 million outpatient visits and 872,000 inpatient admissions. Nearly all children, regardless of geographic location or economic status, are infected with rotavirus before their third birthday, but children in low-income countries are far more vulnerable for Rotavirus infection earlier in life.

Recently, two rotavirus vaccines (Rotavac® and Rotasiil®), developed in India, have been licenced and these Indigenised products have been hailed as pathbreaking public health interventions against rotavirus infections, especially in severe and very severe disease, which may result in death. These vaccines are delivered orally, in three doses, at the ages of 6, 10 and 14 weeks, along with other age-appropriate vaccines.

The Ministry of Health and Family Welfare, Government of India, has recommended that these licentiate vaccines be deployed through the public health system in various states of India in phases, and finally be included in the universal immunization programme (UIP) for all children. In doing so, there remains a chance that some children may receive a mixed dose regimen consisting of both the vaccines. At the request of the Ministry of Health and FW, Govt. of India through ICMR, a clinical trial has been initiated, under the coordinating investigator, Dr. Shanta Dutta, Director and Scientist G, ICMR-National Institute of Cholera and Enteric Diseases, to understand the safety and immunogenicity of such a mixed dose regimen of vaccines. This trial would enrol healthy infants, aged between 6-8 weeks, and randomly assign them to receive either three doses of a single vaccine (Rotavac® or Rotasiil®) or mixed dose regimens consisting of dose combinations of the two vaccines.

The study will enrol children from two cities of India – Kolkata and Pune. The methodology has been thoroughly reviewed and approved by an independent ICMR approved expert committee chaired by eminent and experienced researcher and gastroenterologist Prof. V. I. Mathan. It was formally scrutinized and approved by the Institutional Ethics Committee of each of the study sites, in addition to the "No Objection certificate" from the Central Drugs Standard Control Organization (CDSCO), the national apex regulatory body for Indian pharmaceuticals and medical devices. Further, an independent Data and Safety Monitoring Board (DSMB), constituted by ICMR would oversee the progress of the study, ensure participant safety and review vaccination effect by immune response.

In Kolkata, the participating institute is ICMR-National Institute of Cholera and Enteric Diseases (ICMR-NICED), in collaboration with Dr. BC Roy Children's Hospital and Postgraduate Institute of Paediatric Sciences. If you are the parents or legal guardians of a healthy child, as determined by medical history and clinical examination conducted by the study physicians; if your child is aged less than 6 weeks; if you reside within 5 km of the ICMR-NICED (located at the IDBG Hospital campus) and are likely to remain in the area for about 4-5 months (the duration of the study); and are able and willing to enrol your child in the trial, please get in touch with the following contact persons:

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