

# Clinical Study to Assess the Immunogenicity and Safety of Hexavalent Vaccine Containing Reduced Dose IPV

NCT06413121

---

Status	RECRUITING
Phase	Phase 3
Sponsor	Serum Institute of India Pvt. Ltd.
Enrollment	1,557 participants

## Key Eligibility Criteria

---

### Inclusion (6)

- Male or female infants aged 6-8 weeks at the time of first vaccination.
- Infants with good health, as determined by the medical history, physical examination and clinical judgment of the Investigator.
- Informed consent form signed by at least one parent.
- Infants born at full term pregnancy (e 37 weeks).
- Infants with weight-for-length z-score e -2 standard deviation (SD) at the time of enrolment.

... and 1 more (see full listing online)

### Exclusion (17)

- History of diphtheria/ tetanus/ pertussis/ hepatitis B/ Haemophilus Influenzae type b/ poliomyelitis infection(s).
- Presence of fever e 38°C/ 100.4°F.
- Acute illness of moderate to severe intensity according to the clinical judgment of the investigator .
- Receipt of antibiotics in the past 3 days
- Previous vaccination or planned receipt of any vaccine against diphtheria, tetanus, pertussis, hepatitis B (except birth dose), poliomyelitis (except OPV birth dose) or Haemophilus Influenzae type b infection apart from trial vaccines during the study period.

... and 12 more (see full listing online)

## Locations (9 total)

---

International Centre for Diarrhoeal Disease Research, Bangladesh (ICDDR,B), Dhaka, Bangladesh  
Manipal Academy of Higher Education, Manipal, Mangalore, Karnataka, India  
JSS Medical College and Hospital, Mysore, Karnataka, India  
... and 6 more locations