

# A Phase 3 Study to Evaluate the Immunogenicity and Safety of Minhai's PCV13-DT/TT Vaccine As Compared to Pfizer's PCV13 Vaccine

NCT06608199

---

Status	RECRUITING
Phase	Phase 3
Sponsor	Beijing Minhai Biotechnology Co., Ltd
Enrollment	500 participants

## Key Eligibility Criteria

---

### Inclusion (9)

- Healthy infants based on medical history and clinical assessment.
- Infants age of 6-8 weeks at enrolment. Infants will be eligible since the day they reach 6 weeks of age and until 8 weeks of age included.
- \*Body weight at enrollment  $\geq 3.0$  kg (If the subject does not meet the criteria, the visit may be rescheduled when the criteria is met.).
- \*On the day of vaccination and within 3 days prior to 1st dose of vaccination, axillary temperatures  $\leq 37.5^{\circ}\text{C}/99.1^{\circ}\text{F}$  (If the subject does not meet the criteria, the visit may be rescheduled when the criteria is met.).
- Infant's parent(s) or legal guardian must be able and willing to provide voluntary written/thumb-printed informed consent for the infant to participate in the study.

... and 4 more (see full listing online)

### Exclusion (18)

- Use of any investigational product other than that used in the study prior to randomization or planned use of such a product during the period of study participation.
- History of *S. pneumoniae* infection as confirmed by laboratory testing if available.
- The infant who are children in care, preterm and low-birth-weight (Preterm infants have a gestational age below 37 weeks at birth and low-birth-weight infants have a birth weight below 2.5 kg).
- History of allergic disease or history of a serious reaction to any prior vaccination or known hypersensitivity to any component of the investigational vaccine. And/or all components of the hexavalent vaccine.
- History of anaphylactic shock.

... and 13 more (see full listing online)

## Locations (3 total)

---

Faculty of Medicine Udayana University, Denpasar, Bali, Indonesia  
Universitas Padjadjaran Bandung, Bandung, Bandung, Indonesia  
Faculty of Medicine, padjadjaran University, Bandung, Bandung, Indonesia