

A Study to Evaluate the Immunogenicity and Safety of 13-valent Pneumococcal Conjugate Vaccine (PCV13i) in Healthy Infants Aged 2 Months (Minimum 6 Weeks)

NCT07017777

Status	RECRUITING
Phase	Phase 3
Sponsor	CanSino Biologics Inc.
Enrollment	600 participants

Key Eligibility Criteria

Inclusion (5)

- Healthy infants with stable clinical conditions aged 2 months (42-90 days) at the time of screening, based on medical history and clinical assessment by the investigator. Infants will be eligible starting from the day they turn 6 weeks of age.
- Infant's parent or legal guardian must be able and willing to provide informed consent for the infant's participation in the study.
- Participants and their parent or legal guardian must demonstrate the ability to comply with all trial procedures and be available for the entire follow-up duration.
- The infant's parent or legal guardian must have an easily identifiable and stable place of residence within the study area, be available for the duration of trial participation, and have access to a reliable means of telephone contact for communication with the study team.
- Other reasons for exclusion considered by the investigator.

Exclusion (19)

- Infants born at <35 weeks of gestation.
- Infants who have previously received any pneumococcal vaccine.
- Infants currently participating in or who have recently participated in another interventional clinical trial.
- Infants with an axillary temperature of $\geq 37.8^{\circ}\text{C}$ at the time of enrollment (the participant must be deferred until recovery. The visit may be rescheduled when this criterion is met.)
- Infants with any congenital abnormalities, chronic medical conditions, or genetic disorders, severe malnutrition, inherited disease and others, that in the investigator's judgment, may interfere with the study outcomes.

... and 14 more (see full listing online)

Locations (3 total)

Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand
King Chulalongkorn Memorial Hospital, Bangkok, Thailand
Phramongkutklao Hospital, Bangkok, Thailand

<https://clinicaltrials.gov/study/NCT07017777>

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