

Lot-to-lot Consistency Study of a 21-valent Pneumococcal Conjugate Vaccine in Healthy Infants From 2 Months of Age

NCT07348692

Status	RECRUITING
Phase	Phase 3
Sponsor	Sanofi
Enrollment	2,195 participants

Key Eligibility Criteria

Inclusion (3)

- Aged 42 to 89 days on the day of inclusion
- Participants who are healthy as determined by medical evaluation including medical history and physical examination
- Born at full term of pregnancy (e 37 weeks) and with a birth weight e 2.5 kg or born after a gestation period above 28 (> 28 weeks) through 36 weeks with a birth weight e 1.5 kg, and in both cases medically stable

Exclusion (16)

- Known or suspected congenital or acquired immunodeficiency; or receipt of immunosuppressive therapy, such as anti-cancer chemotherapy or radiation therapy; or long-term systemic corticosteroid therapy
 - History of microbiologically confirmed *Streptococcus pneumoniae* infection or disease
 - Any contraindication to the routine pediatric vaccine being administered in the study
 - History of seizure or significant stable or progressive neurologic disorders such as infantile spasms, inflammatory nervous system diseases, encephalopathy, cerebral palsy
 - Known systemic hypersensitivity to any of the study interventions components, or history of a life-threatening reaction to the study interventions used in the study or to a product containing any of the same substances³
- ... and 11 more (see full listing online)

Locations (3 total)

Investigational Site Number : 3400001, San Pedro Sula, Honduras
Investigational Site Number : 3400002, Tegucigalpa, Honduras
Investigational Site Number : 3400003, Tegucigalpa, Honduras