

# Study of the Safety of a 21-valent Pneumococcal Conjugate Vaccine in Healthy Infants From Approximately 2 Months of Age

NCT06824194

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Status	RECRUITING
Phase	Phase 3
Sponsor	Sanofi
Enrollment	2,320 participants

## Key Eligibility Criteria

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### 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 as assessed by the investigator

### Exclusion (18)

- Participants are excluded from the study if any of the following criteria apply:
- 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
- ... and 13 more (see full listing online)

## Locations (134 total)

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Alabama Clinical Therapeutics - Birmingham - St. Vincent's Drive- Site Number : 8400013, Birmingham, Alabama, United States  
University of Alabama at Birmingham- Site Number : 8400130, Birmingham, Alabama, United States  
Lakeview Clinical Research- Site Number : 8400054, Guntersville, Alabama, United States  
... and 131 more locations