

A Study of 2 Doses of Tetravalent Dengue Vaccine (TDV) in Infants and Toddlers

NCT06665035

Status	RECRUITING
Phase	Phase 3
Sponsor	Takeda
Enrollment	212 participants

Key Eligibility Criteria

Inclusion (6)

- Participant eligibility is determined according to the following criteria:
- Participant is aged ≥ 6 to < 21 months at the time of entry into the trial.
- Participant is male or female.
- Participant is in good health at the time of entry into the trial as determined by medical history, physical examination (including vital signs), and the clinical judgment of the investigator.
- Participant's legally acceptable representative (LAR) has signed and dated a written informed consent form (ICF) and any required privacy authorization prior to the initiation of any trial procedure, and after the nature of the trial has been explained according to local regulatory requirements.

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

Exclusion (29)

- Any participant who meets any of the following criteria will not qualify for randomization:
- Participant has contraindication(s), warning(s) and/or precaution(s) applicable to vaccination with TDV as specified in the investigator's brochure (IB) and/or the approved product label (as applicable) in the participating country.
- Participant has a known hypersensitivity or allergy to any of the investigational medicinal product (IMP) components (including excipients).
- Participant has behavioral or cognitive impairment or psychiatric disease that, in the opinion of the investigator, may interfere with the participant's ability to participate in the trial.
- Participant has a history of progressive or severe neurologic disorder, seizure disorder or neuro-inflammatory disease (example, Guillain-Barré syndrome).

... and 24 more (see full listing online)

Locations (4 total)

Clinica de la Costa Ltda, Barranquilla, Atlántico, Colombia
Centro de Estudios en Infectología Pediátrica S.A.S, Cali, Valle del Cauca Department, Colombia
King Chulalongkorn Memorial Hospital, Pathum Wan, Bangkok, Thailand

... and 1 more locations