Butantan-DV Vaccine in Elderly Populations (DEN-04-IB)

NCT06891950

Status	RECRUITING
Phase	Phase 3
Sponsor	Butantan Institute
Enrollment	997 participants

Key Eligibility Criteria

Inclusion (4)

- a. Healthy participants aged between 40 and 79 years at the time of study entry, with or without a history of exposure to dengue fever;
- b. Agree to periodic contact by telephone, electronic means, and home visits and to the research center;
- c. Participants with reproductive potential must be using some effective contraceptive method at screening and continue using it for up to 90 days after the intervention; except in cases where the volunteer declares that she is not at risk of becoming pregnant, either by not engaging in sexual activities or by engaging in them in a non-reproductive manner, up to 90 days after vaccination;
- d. Demonstrate intent to participate in the study, documented by the participant's signature of the informed consent form, as well as the study procedures, including completing the Participant Diaries, blood collection, and being available for scheduled study visits and contacts.

Exclusion (16)

- a. For female participants with reproductive potential: pregnancy (confirmed by positive ²hCG test), breastfeeding or manifest intention to have sexual practices with reproductive potential without using a contraceptive method in the 90 days following vaccination;
- b. Planned donation of blood, semen or eggs in the 90 days following vaccination;
- c. Evidence of active uncontrolled neurological, cardiac, pulmonary, hepatic or renal disease according to anamnesis or physical examination, at the discretion of the investigator;
- d. Diseases that compromise the immune system, including: decompensated diabetes mellitus, active neoplasms or history of neoplasms in the last five years (except basal cell carcinoma), congenital or acquired immunodeficiencies (including HIV/AIDS), solid organ transplants (heart, liver, pancreas, lung, kidney) or uncontrolled autoimmune diseases according to anamnesis or physical examination, as well as a history of liver failure, heart failure or terminal chronic kidney disease or dialysis;
- e. Behavioral, cognitive, or psychiatric illness that, in the opinion of the principal investigator or his/her medical representative, affects the potential participant's ability to understand and comply with the requirements of the study protocol;

... and 11 more (see full listing online)

Locations (5 total)

CWB 02 - Centro Médico São Francisco, Curitiba, Paraná, Brazil
PET 01 - Hospital Escola da Universidade de Pelotas - HEUFPEL, Pelotas, Rio Grande do Sul, Brazil
POA 05 - Núcleo de Pesquisa do Rio Grande do Sul, Porto Alegre, Rio Grande do Sul, Brazil
... and 2 more locations