

Safety and Immunogenicity of the Monovalent Influenza Vaccine A (H5N8) (Inactivated, Fragmented and Adjuvanted) in Adults and Older Adults

NCT06842173

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Butantan Institute
Enrollment	700 participants

Key Eligibility Criteria

Inclusion (6)

- Males and non-pregnant females aged e 18 years at the time of the first study vaccination.
- Be in good health and clinically stable (defined as having no pre-existing health condition or having a pre-existing health condition that has not required a change in treatment or hospitalization for worsening of disease in the 3 months prior to the date of the first study vaccination).
- Agree to participate in the study and provide written informed consent prior to the initiation of any study procedures.
- Be able and willing to comply with all study procedures, including completing Participant Diaries, collecting blood samples, and being available for scheduled study visits and contacts.
- For females of childbearing potential, have a negative pregnancy test prior to the first study vaccination.

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

Exclusion (27)

- Having received any vaccine (including seasonal influenza) 28 days prior to the date of the first study vaccination or having any vaccination in the period from the first vaccination to the immune response assessment visit after the last vaccination.
- Known hypersensitivity or allergy to eggs, chicken proteins, squalene-based adjuvants, or any other component of the investigational product.
- History of serious adverse reaction or anaphylaxis to any previous influenza vaccine (licensed or not).
- Having received any influenza A/H5 vaccine or history of exposure to avian influenza A/H5.
- Presence of a bleeding disorder or any condition that contraindicates intramuscular injection.

... and 22 more (see full listing online)

Locations (5 total)

Centro de Terapias Avançadas E Inovadoras - Ct Terapias/Ufmg, Belo Horizonte, Minas Gerais, Brazil

Plátano Centro de Pesquisa Clínica LTDA, Recife, Pernambuco, Brazil

Fundação Faculdade Regional de Medicina de São Jose do Rio Preto - (Centro integrado de Pesquisa CIP), São José do Rio Preto, São Paulo, Brazil

... and 2 more locations