A Study on the Safety and Immune Response of Investigational mRNA Seasonal Flu/COVID-19 Combination Vaccine in Adults

NCT07464314

Status	RECRUITING
Phase	Phase 1
Sponsor	GlaxoSmithKline
Enrollment	225 participants

Key Eligibility Criteria

Inclusion (4)

- Participants, who, in the opinion of the investigator, can and will comply with the requirements of the protocol independently or with the assistance of the caregiver.
- Informed consent obtained from the participant prior to performance of any study-specific procedure.
- A male or female 65 to 85 years of age (YoA) (inclusive) at the time of screening.
- Healthy participants or medically stable patients as established by medical history and clinical examination.

Exclusion (14)

- Any clinically significant laboratory abnormality.
- History of symptomatic influenza/ SARS-CoV-2 infection confirmed by local health authority-approved testing methods within 180 days (for influenza) or 90 days (SARS-CoV-2 infection) prior to study intervention administration.
- History of Guillain-Barré syndrome (GBS) within 6 weeks of receiving any vaccine.
- Current or past malignancy, unless completely resolved without clinically significant sequelae (e.g., no evidence of disease following successful treatment of basal cell carcinoma cases are allowed) for \>5 years.
- Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required).

... and 9 more (see full listing online)

Locations (2 total)

GSK Investigational Site, San Diego, California, United States
GSK Investigational Site, Miami, Florida, United States