

The Progressive Supranuclear Palsy Clinical Trial Platform

Status: RECRUITING

Eligibility Criteria

Age: 41 years to 86 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

Inclusion Criteria:

1. Clinical diagnosis of possible or probable PSP Richardson's Syndrome as defined by the 2017 Movement Disorder Society (MDS) criteria. 2. Presence of PSP symptoms for ≤ 5 years at screening (based on the best judgment of the site PI). 3. Mini-Mental State Examination (MMSE) score at screening of ≥ 25 . 4. Able to walk at least 10 steps with minimal assistance (e.g., one arm for safety, but not postural support). 5. Stable doses of permitted medications as described per protocol for 30 days prior to screening. 6. Resides at home or in the community (assisted living is acceptable). 7. As assessed by the site PI, participant is likely to be able to comply with the protocol for the duration of the study, and has adequate vision, hearing (hearing aid permitted), and literacy (English or Spanish) sufficient for compliance with the required testing procedures.

Exclusion Criteria:

1. Females who are breastfeeding or pregnant (as documented by a urine pregnancy test) during screening, or plan to become pregnant during the study. 2. Females of childbearing potential who did not use a highly effective method of contraception within 28 days of screening and/or are not willing to use a highly effective method of contraception for the duration of their participation in the study. 3. Lacks good venous access such that multiple blood draws would be precluded. 4. Weighs less than 40kg, or more than 136kg at screening. 5. Blood transfusion within 4 weeks of screening. 6. Contraindications to MRI studies, including metal (ferromagnetic) implants, a cardiac pacemaker that is not compatible with MRI, and/or severe claustrophobia. 7. Screening MRI scan showing structural evidence of alternative pathology not consistent with PSP that could explain a substantial portion of the participant's symptoms as indicated by the central MRI read. 8. Any unstable and/or clinically significant medical condition likely to hamper the evaluation of safety and/or efficacy of study drug (e.g., clinically significant reduction in serum B12 or folate levels, clinically significant abnormalities of thyroid function, stroke, or other cerebrovascular or cardiovascular conditions), as per the site PI's judgment. 9. History of severe allergic reaction (e.g., anaphylaxis) including but not limited to: severe allergic reaction to previous vaccines, foods, and/or medications. 10. Hospitalization within 30 days prior to screening or baseline. 11. Infections or major surgical procedures within 3 months prior to screening, judged to be clinically significant by the site PI. 12. Myocardial infarction within 1 year prior to baseline, unstable angina pectoris, symptomatic congestive heart failure. 13. History of cancer within the past 5 years other than treated skin squamous cell carcinoma, basal cell carcinoma, and melanoma in-situ, localized prostate cancer not requiring treatment, or prostate or breast cancer, which have been fully removed and are considered cured. 14. History or presence of immunological or inflammatory conditions, including neurological disorders, meningitis or meningoencephalitis. 15. History or presence of epilepsy requiring ongoing use of antiepileptic medications. Antiepileptic medications are permitted for pain or psychiatric use per the protocol. 16. DSM-5 criteria for drug or alcohol abuse or dependence currently met within the past 5 years. 17. Clinically significant abnormal vital signs including sustained sitting blood pressure $> 160/100$ mm Hg. 18. Diabetes mellitus with hemoglobin A1c (HbA1c) levels of $\geq 8.0\%$. 19. Known history of human immunodeficiency virus (HIV-1 or 2). 20. Known history of acute/chronic hepatitis B or C unless treated curatively.

Conditions & Interventions

Interventions:

BIOLOGICAL: AADvac1, DRUG: LM11A-31

Conditions:

Progressive Supranuclear Palsy(PSP)

Keywords:

PSP, Placebo-Controlled, Double-Blind, Master Protocol

More Information

Contact(s): PSP Trial Platform Team - psptrialplatform@ucsf.edu

Principal Investigator:

IRB

Number:

System ID: NCT07173803

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