

Safety and Tolerability Study of ST-503 for Refractory Pain Due to Peripheral Neuropathy (Small Fiber Predominant, SFN)

NCT06980948

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| Status | RECRUITING |
| Phase | Phase 1, Phase 2 |
| Sponsor | Sangamo Therapeutics |
| Enrollment | 27 participants |

Key Eligibility Criteria

Inclusion (14)

- Signed and dated informed consent document indicating that the subject (or a legal representative) has been informed of all pertinent aspects of the study.
- e 18years of age.
- Diagnostic characterization of peripheral neuropathy (small fiber predominant) according to the Analgesic, Anesthetic, and Addiction Clinical Trial Translations, Innovations, Opportunities and Networks (ACTION) criteria.
- a. Minimal large fiber polyneuropathy by clinical examination and by nerve conduction studies (NCS) during screening. NCS results may be based on unilateral assessment. However, bilateral SNAP responses must be within normal range for age and gender in the ulnar, radial, and sural nerves to enhance sensitivity of monitoring for DRG ganglionopathy post ST-503 dosing or sham procedure treatment. Only persons with normal SNAP responses may be enrolled.
- An IENFD punch skin biopsy demonstrating reduction below the 5th percentile of sex and age-adjusted normal values must be performed and sent for IENFD evaluation at the Cutaneous Nerve Lab at University of Utah.

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

Exclusion (59)

- Serum sample positive for pre-existing anti-AAV9 antibodies per predefined cut point based on assay sensitivity.
- Drug- and alcohol-related:
- Persons using opioid analgesics for under 3 months or persons who are not on a stable dose of opioids; if on a stable dose, the dose may decrease over the course of the study but should not be increased.
- History of known alcohol abuse, opioid analgesic abuse, or illicit drug abuse within 2 years of Screening.
- Positive urine test for drugs of abuse (including opiates, benzodiazepines, amphetamines, cocaine, barbiturates, and phencyclidine) without prescription and investigator approval, at Screening and Day -1.

... and 54 more (see full listing online)

Locations (10 total)

HonorHealth, Scottsdale, Arizona, United States
University of Arkansas for Medical Sciences, Little Rock, Arkansas, United States
Johns Hopkins University, Baltimore, Maryland, United States

... and 7 more locations

<https://clinicaltrials.gov/study/NCT06980948>

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