HEALEY ALS Platform Trial - Master Protocol

NCT04297683

Status	RECRUITING
Phase	Phase 2, Phase 3
Sponsor	Merit E. Cudkowicz, MD
Enrollment	1,500 participants

Key Eligibility Criteria

Inclusion (9)

- Sporadic or familial ALS diagnosed as clinically possible, probable, lab-supported probable, or definite ALS defined by revised El Escorial criteria.
- Age 18 years or older.
- Capable of providing informed consent and complying with study procedures, in the SI's opinion.
- Time since onset of weakness due to ALS d 24 months at the time of the Master Protocol Screening Visit.
- Vital Capacity e 50% of predicted capacity at the time of the Master Protocol Screening Visit measured by Slow Vital Capacity (SVC), or, if required due to pandemic-related restrictions, Forced Vital Capacity (FVC) measured in person.

... and 4 more (see full listing online)

Exclusion (9)

- Clinically significant unstable medical condition (other than ALS) that would pose a risk to the participant, according to SI's judgment (e.g., cardiovascular instability, systemic infection), or clinically significant laboratory abnormality or EKG changes. Clinically significant abnormal liver or kidney function is exclusionary. The following values \[alanine aminotransferase (ALT) or aspartate aminotransferase (AST) \> 3 times the upper limit of normal (ULN) or estimated Glomerular Filtration Rate (eGFR) \< 30 mL/min/1.73m2\] are exclusionary regardless of clinical symptoms.
- Presence of unstable psychiatric disease, cognitive impairment, dementia or substance abuse that would impair ability of the participant to provide informed consent, in the SI's opinion.
- Active cancer or history of cancer, except for the following: basal cell carcinoma or successfully treated squamous cell carcinoma of the skin, cervical carcinoma in situ, prostatic carcinoma in situ, or other malignancies curatively treated and with no evidence of disease recurrence for at least 3 years.
- Use of investigational treatments for ALS (off-label use or active participation in a clinical trial) within 5 half-lives (if known) or 30 days (whichever is longer) prior to the Master Protocol Screening Visit.
- Exposure at any time to any gene therapies under investigation for the treatment of ALS (off-label use or investigational).

... and 4 more (see full listing online)

Locations (74 total)

Barrow Neurological Institute, Phoenix, Arizona, United States
Mayo Clinic Scottsdale, Scottsdale, Arizona, United States
University of Arkansas for Medical Sciences, Little Rock, Arkansas, United States
... and 71 more locations