



MEMBER INITIATED STUDIES

Study 'Nick name'	Full study name	Principal Investigators	Type Of Clinical Trial	Expected # of participants	# of Sites	No. of in - person visits	Investigational drug	Enrollment Criteria		Currently enrolling?
								Age criteria	ALS Type	
Biomarkers	A Multicenter Study for the Validation of ALS Biomarkers	Merit Cudkowicz and Swati Aggarwal MGH	Observational	650	31	1 to 5 in 18 months	None	30-80 years of age	Familial Sporadic	Yes
Ceftriaxone	Clinical Trial of Ceftriaxone in Subjects with Amyotrophic Lateral Sclerosis (ALS) – Stage III	Merit Cudkowicz and Swati Aggarwal MGH Jeremy Shefner SUNY	Interventional	600	58	~ 1 visit every 4weeks; variable duration	Ceftriaxone	18 +	Familial Sporadic	Yes
Pre- fALS	The Pre-Familial Amyotrophic Lateral Sclerosis (Pre-fALS) Study	Michael Benetar Emory	Observational	30	1	1 visit per year	None	18 +	Asymptomatic Familial ALS Pedigree	Yes
Arimoclomol	Phase II/III Randomized, Placebo-Controlled Trial of Arimoclomol in SOD1 Positive Familial Amyotrophic Lateral Sclerosis	Michael Benetar Emory	Interventional	80	2	2	Arimoclomol	18 +	Familial	Yes
ATLIS	Validation of a New Device to Measure Neuromuscular Disease Progression	Patricia Andres MGH	Observational	70	4	1 -3	None	18 +	Familial Sporadic	Yes
Nutritional Study	Trial of High fat/High Calorie Diet versus Optimal Nutrition in Amyotrophic Lateral Sclerosis	Anne Marie Wills MGH	Interventional	60	6	5	Nutritional Supplements (Oxepa, Jevity 1.0 and Jevity 1.5)	18 +	Familial Sporadic	Yes
Biopsy Study	Generation and Characterization of Cell Lines for Amyotrophic Lateral	Nick Maragakis, and Jeffrey Rothstein IHU	Observational	25	1	1	None	18+	Familial SOD1 pos	Yes



INDUSTRY SPONSORED STUDIES

Study 'Nick name'	Full study name	Principal Investigators	Type Of Clinical Trial	Expected # of participants	# of sites	# of in - person visits	Investigational drug	Enrollment Criteria		Currently enrolling?
								Age criteria	ALS Type	
Knopp	An Open-Label, Safety and Tolerability, Study Evaluating KNS-760704 in Patients with Amyotrophic Lateral Sclerosis	Merit Cudkowicz MGH	Interventional	Up to 94	19	14	KNS-760704	18+	Familial Sporadic	No. Enrollment Completed
ISIS	A Phase 1, Double-Blind, Placebo-Controlled, Dose-Escalation Study of the Safety, Tolerability, and Pharmacokinetics of ISIS 333611 Administered Intrathecally to Patients with Familial Amyotrophic Lateral Sclerosis Due to superoxide Dismutase 1 Gene Mutations	Tim Miller Wash. U. and Merit Cudkowicz MGH	Interventional	32	6	6	Antisense oligo ISIS 333611	18 +	Familial	Yes
NeuralStem, Inc.	A Phase I, Open-Label, First-in-Human, Feasibility and Safety Study of Human Spinal Cord Derived Neural Stem Cell Transplantation for the Treatment of Amyotrophic Lateral Sclerosis	NeuralStem	Interventional	Up to 18	1	Varies (approx, 16 in first year)	NSI-566RSC (Human Spinal Stem Cells)	18+	Familial Sporadic	Yes

For more information on any of the studies listed above please visit http://www.nealsconsortium.org/neals_clinical_research.html
or www.clinicaltrials.gov