ClinicalTrials.gov Search Results 08/08/2018

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
1	NCT03613038	A Systematic Investigation of Phonetic Complexity Effects on Articulatory Motor Performance in Progressive Dysarthria Study Documents:	Title Acronym: Other Ids: •1209643 •1R15DC016383-01	Recruiting	•Amyotrophic Lateral Sclerosis •Parkinson Disease	•Behavioral: Phonetic complexity effects on speech motor performance	Study Type: Interventional Phase: Not Applicable Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Basic Science Outcome Measures: •Peak movement speed •Range of movement •Duration •Spatiotemporal movement variability (STI) •Inter-articulator coordination	Enrollment: 150 Age: 19 Years to 90 Years (Adult, Older Adult) Sex: All	•University of Missouri-Columbia •National Institute on Deafness and Other Communication Disorders (NIDCD)	•Other •NIH	Study Start: July 15, 2017 Primary Completion: January 31, 2020 Study Completion: July 14, 2020 First Posted: August 2, 2018 Results First Posted: No Results Posted Last Update Posted: August 3, 2018	•University of Kansas Medical Center, Fairway, Kansas, United States •University of Missouri-Columbia, Columbia, Missouri, United States
2	NCT03519880	A Pilot Study of the Utility of 3D Printed Masks for ALS Subjects Study Documents:	Title Acronym: Other Ids: HUM00112433	Enrolling by invitation	•Amyotrophic Lateral Sclerosis	•Device: Custom Mask Interface	Study Type: Interventional Phase: Not Applicable Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Device Feasibility Outcome Measures: •Average number of hours the custom NIV mask interface is used per night •Leak parameters from device •Tidal volume measurements •Interviews with subjects regarding their experience with the custom mask Qualitative assessment of custom NIV mask efficacy	Enrollment: 40 Age: 18 Years and older (Adult, Older Adult) Sex: All	•University of Michigan •ALS Association	•Other	Study Start: March 14, 2017 Primary Completion: April 2020 Study Completion: April 2021 First Posted: May 9, 2018 Results First Posted: No Results Posted Last Update Posted: May 9, 2018	•Michigan Medicine, Ann Arbor, Michigan, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
3	NCT03516994	Reducing Disparities in the Quality of Advance Care Planning for Older Adults Study Documents:	Title Acronym: EQUALACP Other Ids: •Pro00091633 •OLC-1609-36381	Not yet recruiting	•Metastatic Cancer •Congestive Heart Failure •Chronic Obstructive Pulmonary Disease •Parkinson Disease •Interstitial Lung Disease •Amyotrophic Lateral Sclerosis •End Stage Liver Disease •End Stage Renal Disease •Diabetes Complications	•Behavioral: Respecting Choices First Steps •Behavioral: Five Wishes Form	Study Type: Interventional Phase: Not Applicable Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: None (Open Label) •Primary Purpose: Other Outcome Measures: •Proportion of African Americans who complete advance care planning •Proportion of Whites who complete advance care planning •Difference in Proportion of Whites versus African Americans who complete advance care planning •Patient Readiness to Engage in Advance Care Planning •Patient Quality of Life	Enrollment: 800 Age: 65 Years and older (Older Adult) Sex: All	•Duke University	•Other	Study Start: August 1, 2018 Primary Completion: September 1, 2022 Study Completion: September 1, 2022 First Posted: May 7, 2018 Results First Posted: No Results Posted Last Update Posted: May 8, 2018	•University of Alabama at Birmingham, Birmingham, Alabama, United States •Emory University, Atlanta, Georgia, United States •University of South Carolina, Columbia, South Carolina, United States •University of Texas Southwestern, Dallas, Texas, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
4	NCT03505021	Effects of Oral Levosimendan (ODM-109) on Respiratory Function in Patients With ALS Study Documents:	Title Acronym: REFALS Other Ids: 3119002	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: Levosimendan •Drug: Placebo for levosimendan	Study Type: Interventional Phase: Phase 3 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •Supine slow vital capacity SVC •Combined assessment of Revised ALS Functional Rating Scale ALSFRS-R function and survival through 48 weeks •Time to respiratory event through 48 weeks •Clinical Global Impression CGI at 48 weeks •Change from baseline in respiratory function of ALSFRS-R at 48 weeks	Enrollment: 450 Age: 18 Years to 120 Years (Adult, Older Adult) Sex: All	•Orion Corporation, Orion Pharma	•Industry	Study Start: June 21, 2018 Primary Completion: August 30, 2020 Study Completion: October 30, 2020 First Posted: April 20, 2018 Results First Posted: No Results Posted Last Update Posted: July 17, 2018	•Neuromuscular Research Center and Neuromuscular Clinic of Arizona, Phoenix, Arizona, United States •Colorado Springs Neurological Associates, Colorado Springs, Colorado, United States •Hospital of Special Care, New Britain, Connecticut, United States •The George Washington Medical Faculty Associates - Foggy Bottom North Pavilion, Washington, District of Columbia, United States •Providence Holy Cross Medical Center, Fort Lauderdale, Florida, United States •University of Florida Health - Jacksonville, Jacksonville, Florida, United States •University of South Florida, Tampa, Florida, United States •Emory University School of Medicine, Atlanta, Georgia, United States •University of Kentucky Chandler Medical Center, Lexington, Kentucky, United States •Massachusetts General Hospital, Boston, Massachusetts, United States •and 36 more

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
5	NCT03488524	Open Label Extension Study of AMX0035 in Patients With ALS Study Documents:	Title Acronym: CENTAUR-OLE Other Ids: AMX-3500-OLE	Recruiting	• Amyotrophic Lateral Sclerosis • ALS	• Drug: AMX0035	Study Type: Interventional Phase: Phase 2 Study Design: • Intervention Model: Single Group Assignment • Masking: None (Open Label) • Primary Purpose: Treatment Outcome Measures: • Quantity of adverse events and serious adverse events observed in the study • Hospitalizations • Rate of Progression on the Amyotrophic Lateral Sclerosis Rating Scale Revised (ALSFRS-R) • Rate of Progression on ATLIS Strength Measurement • Rate of Progression on Slow Vital Capacity • Gastric Tube Frequency • Permanent Invasive Ventilation	Enrollment: 132 Age: Child, Adult, Older Adult Sex: All	• Amylyx Pharmaceuticals Inc. • Massachusetts General Hospital Neurology Clinical Research Institute	• Industry • Other	Study Start: March 29, 2018 Primary Completion: January 1, 2020 Study Completion: January 1, 2020 First Posted: April 5, 2018 Results First Posted: No Results Posted Last Update Posted: April 13, 2018	• Massachusetts General Hospital, Boston, Massachusetts, United States • University of Massachusetts Memorial Medical Center, Worcester, Massachusetts, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
6	NCT03474263	IC14 for Rapidly Progressive Amyotrophic Lateral Sclerosis (ALS) Study Documents:	Title Acronym: Other Ids: ALS02	Not yet recruiting	•Amyotrophic Lateral Sclerosis	•Biological: Biologic: IC14 (monoclonal antibody against human CD14)	Study Type: Interventional Phase: Phase 2 Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •Glial Activation •Serum neurofilament •Urinary p75 neurotrophin receptor •Safety •Immunogenicity •Pharmacokinetics •Pharmacodynamics	Enrollment: 20 Age: 18 Years to 80 Years (Adult, Older Adult) Sex: All	•Implicit Bioscience •Massachusetts General Hospital	•Industry •Other	Study Start: September 1, 2018 Primary Completion: April 12, 2020 Study Completion: July 12, 2020 First Posted: March 22, 2018 Results First Posted: No Results Posted Last Update Posted: April 18, 2018	•Neurological Clinical Research Institute (NCRI), Boston, Massachusetts, United States
7	NCT03472950	Safety and Efficacy of Ranolazine for the Treatment of Amyotrophic Lateral Sclerosis Study Documents:	Title Acronym: Other Ids: STUDY00141491	Recruiting	•ALS	•Drug: Ranolazine 500 MG •Drug: Ranolazine 1000 MG	Study Type: Interventional Phase: Phase 2 Study Design: •Allocation: Non-Randomized •Intervention Model: Sequential Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •Dose limiting toxicities (DLT) •Cramp Questionnaire •Fasciculation frequency on muscle ultrasound •Cramp potential duration	Enrollment: 20 Age: 18 Years and older (Adult, Older Adult) Sex: All	•University of Kansas Medical Center •Gilead Sciences	•Other •Industry	Study Start: June 11, 2018 Primary Completion: June 11, 2019 Study Completion: June 11, 2019 First Posted: March 21, 2018 Results First Posted: No Results Posted Last Update Posted: June 19, 2018	•University of Kansas Medical Center, Kansas City, Kansas, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
8	NCT03457753	Riluzole Oral Soluble Film Safety and Tolerability in Amyotrophic Lateral Sclerosis Study Documents:	Title Acronym: Other Ids: 17MO1R-0016	Not yet recruiting	•ALS	•Drug: Riluzole Oral Soluble Film	Study Type: Interventional Phase: Phase 2 Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Other Outcome Measures: Change from baseline in NCI-CTC score at week 12	Enrollment: 25 Age: 18 Years to 80 Years (Adult, Older Adult) Sex: All	•Aquestive Therapeutics •Inventiv Health •Covance	•Industry •Other	Study Start: March 2018 Primary Completion: September 2018 Study Completion: October 2018 First Posted: March 8, 2018 Results First Posted: No Results Posted Last Update Posted: March 21, 2018	•University of Florida Medical Center, Gainesville, Florida, United States •Neurology Associates, P.C., Lincoln, Nebraska, United States •Texas Neurology, P.A., Dallas, Texas, United States
9	NCT03456882	The Effect of RNS60 on ALS Biomarkers Study Documents:	Title Acronym: RNS60 Other Ids: RNS60	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: RNS60	Study Type: Interventional Phase: Phase 2 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Primary Purpose: Other Outcome Measures: •Pharmacodynamic biomarkers •ALSFRS-R scale •Survival •Forced Vital Capacity (FVC) •Incidence of adverse event (Tolerability) related to RNS60 •Quality of life	Enrollment: 142 Age: 18 Years to 70 Years (Adult, Older Adult) Sex: All	•Mario Negri Institute for Pharmacological Research •ALS Association •Get out ONLUS	•Other	Study Start: November 18, 2016 Primary Completion: April 30, 2019 Study Completion: April 30, 2019 First Posted: March 7, 2018 Results First Posted: No Results Posted Last Update Posted: June 8, 2018	•Massachusetts General Hospital, Boston, Massachusetts, United States •Azienda Opsedaliera Universitaria Consorziale Policlinico- Università degli studi di Bari, Bari, Italy •Spedali civili di Brescia, Brescia, Italy •ASST Valle Olona Presidio ospedaliero Gallarate, Gallarate, Italy •IRCCS Azienda Ospedaliera Universitaria San Martino IST, Genova, Italy •Ospedale San Raffaele, Miano, Italy •Centro Clinico NEMO - Fondazione Serena Onlus, Milano, Italy •Presidio Ospedaliero Provinciale - Nuovo Ospedale Civile "S. Agostino Estense", Modena, Italy •Azienda Ospedaliera Universitaria della Seconda Univ. Degli Studi di Napoli (AOU-SUN), Napoli, Italy •Azienda Ospedaliero Universitaria Maggiore della Carità, Novara, Italy •and 10 more

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
10	NCT03411863	Cervical Electrical Stimulation for ALS Study Documents:	Title Acronym: Other Ids: B2527-P	Recruiting	•Amyotrophic Lateral Sclerosis	•Device: CES at rest •Device: CES plus active hand or wrist movements	Study Type: Interventional Phase: Not Applicable Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Basic Science Outcome Measures: •Electromyographic responses (rest) •Electromyographic responses (active)	Enrollment: 50 Age: 21 Years to 65 Years (Adult, Older Adult) Sex: All	•VA Office of Research and Development	•U.S. Fed	Study Start: January 4, 2018 Primary Completion: December 31, 2019 Study Completion: May 29, 2020 First Posted: January 26, 2018 Results First Posted: No Results Posted Last Update Posted: July 20, 2018	•James J. Peters VA Medical Center, Bronx, NY, Bronx, New York, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
11	NCT03334786	Study to Evaluate Safety & Efficacy of FLX-787-ODT to Treat Fasciculations in Tongue and Appendicular Muscle in Adult Subjects With ALS Study Documents:	Title Acronym: Other Ids: FLX-787-107	Recruiting	•Amyotrophic Lateral Sclerosis •Fasciculation	•Drug: FLX-787-ODT	Study Type: Interventional Phase: •Phase 1 •Phase 2 Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •Change from Baseline of Diastolic Blood Pressure in mmHg •Change from Baseline of Systolic Blood Pressure in mmHg •Change from Baseline in Heart Rate in beats per minute •Change from Baseline in Respiration Rate in breaths per minute •Change from Baseline in Body Temperature in degrees Celsius or Fahrenheit •Change from Baseline of Oral Cavity Examination •Incidence of Treatment-Emergent Adverse Events •Change from Baseline of Fasciculation Frequency •Change from Baseline in Peak Tongue Strength in kPa by Iowa Oral Performance Instrument •Change from Baseline in Speech Assessments •Change from Baseline in Swallowing Assessments	Enrollment: 15 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Flex Pharma, Inc.	•Industry	Study Start: April 5, 2018 Primary Completion: August 2018 Study Completion: August 2018 First Posted: November 7, 2017 Results First Posted: No Results Posted Last Update Posted: April 11, 2018	•Beth Israel Deaconess Medical Center, Boston, Massachusetts, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
12	NCT03280056	Safety and Efficacy of Repeated Administrations of NurOwn® in ALS Patients Study Documents:	Title Acronym: Other Ids: BCT-002-US	Recruiting	•Amyotrophic Lateral Sclerosis (ALS)	•Biological: NurOwn® (MSC-NTF cells) •Other: Placebo	Study Type: Interventional Phase: Phase 3 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •To evaluate the efficacy and safety of NurOwn® (autologous MSC-NTF cells) as compared to placebo as measured by the amyotrophic lateral sclerosis functional rating scale (ALSFRS-R) •Biomarkers	Enrollment: 200 Age: 18 Years to 60 Years (Adult) Sex: All	•Brainstorm-Cell Therapeutics •California Institute for Regenerative Medicine	•Industry •Other	Study Start: August 28, 2017 Primary Completion: April 30, 2019 Study Completion: July 30, 2019 First Posted: September 12, 2017 Results First Posted: No Results Posted Last Update Posted: May 25, 2018	•University of California Irvine Alpha Stem Cell Clinic, Irvine, California, United States •Cedars-Sinai Medical Center, Los Angeles, California, United States •California Pacific Medical Center, San Francisco, California, United States •Massachusetts General Hospital, Boston, Massachusetts, United States •University of Massachusetts Medical School, Worcester, Massachusetts, United States •Mayo Clinic, Rochester, Minnesota, United States
13	NCT03268603	Intrathecal Autologous Adipose-derived Mesenchymal Stromal Cells for Amyotrophic Lateral Sclerosis (ALS) Study Documents:	Title Acronym: Other Ids: •15-008008 •UL1TR000135	Recruiting	•ALS •Amyotrophic Lateral Sclerosis	•Drug: Autologous Adipose-derived Mesenchymal Stromal Cells	Study Type: Interventional Phase: Phase 2 Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •Number of Adverse Events •Change in slope of ALS Functional Rating Scale - Revised (ALSFRS-R)	Enrollment: 60 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Mayo Clinic •State of Minnesota Regenerative Medicine Minnesota	•Other	Study Start: October 10, 2017 Primary Completion: December 2019 Study Completion: December 2019 First Posted: August 31, 2017 Results First Posted: No Results Posted Last Update Posted: January 30, 2018	•Mayo Clinic in Rochester, Rochester, Minnesota, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
14	NCT03201991	ALS Study Determining Various Biomarkers and Strength Comparison After Exercise Study Documents:	Title Acronym: ADVANCE Other Ids: STUDY00003843	Recruiting	•Amyotrophic Lateral Sclerosis	•Other: Resistance Exercise Program	Study Type: Interventional Phase: Not Applicable Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Prevention Outcome Measures: Change in functional muscle strength	Enrollment: 7 Age: 18 Years and older (Adult, Older Adult) Sex: All	•University of Kansas Medical Center	•Other	Study Start: May 1, 2017 Primary Completion: May 1, 2018 Study Completion: May 1, 2018 First Posted: June 28, 2017 Results First Posted: No Results Posted Last Update Posted: June 28, 2017	•University of Kansas Medical Center, Kansas City, Kansas, United States
15	NCT03202017	Lung Volume Recruitment Combined With Expiratory Muscle Strength Training in ALS Study Documents:	Title Acronym: Other Ids: NEUR-2017-25778	Recruiting	•Amyotrophic Lateral Sclerosis	•Procedure: Expiratory Muscle Strength Training (EMST) •Procedure: EMST + Lung Volume Recruitment (LVR)	Study Type: Interventional Phase: Not Applicable Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Single (Outcomes Assessor) •Primary Purpose: Supportive Care Outcome Measures: •Peak Cough Flow •Maximal Expiratory Pressure •Forced Vital Capacity •Eating Assessment Tool - 10 (EAT-10) •Swallowing Related Quality of Life (SWAL-QOL) •Speech Intelligibility Test (SIT)	Enrollment: 24 Age: 18 Years and older (Adult, Older Adult) Sex: All	•University of Minnesota - Clinical and Translational Science Institute	•Other	Study Start: March 1, 2018 Primary Completion: December 2020 Study Completion: December 2021 First Posted: June 28, 2017 Results First Posted: No Results Posted Last Update Posted: May 7, 2018	•University of Florida, Gainesville, Florida, United States •University of Minnesota, Minneapolis, Minnesota, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
16	NCT03168711	Safety of Urate Elevation in Amyotrophic Lateral Sclerosis (ALS) Study Documents:	Title Acronym: SURE-ALS2 Other Ids: SURE-ALS2	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: Inosine •Drug: Placebo	Study Type: Interventional Phase: Phase 2 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •Safety Will be Assessed by the Occurrence of Adverse Events •Tolerability to Complete the Entire 20 Week Study on Study Drug	Enrollment: 30 Age: 18 Years to 85 Years (Adult, Older Adult) Sex: All	•Massachusetts General Hospital •The Salah Foundation •MGH cure ALS Fund	•Other	Study Start: October 1, 2017 Primary Completion: October 2019 Study Completion: January 2020 First Posted: May 30, 2017 Results First Posted: No Results Posted Last Update Posted: February 1, 2018	•Holy Cross Hospital, Fort Lauderdale, Florida, United States •Massachusetts General Hospital, Boston, Massachusetts, United States •University of Minnesota, Minneapolis, Minnesota, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
17	NCT03160898	A Study to Evaluate Efficacy, Safety and Tolerability of CK-2127107 in Patients With Amyotrophic Lateral Sclerosis (ALS) Study Documents:	Title Acronym: FORTITUDE-ALS Other Ids: CY 5022	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: CK-2127107 •Drug: Placebo	Study Type: Interventional Phase: Phase 2 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •Change from baseline to Week 12 in the percent predicted slow vital capacity (SVC) •Slope of change from baseline in the mega-score of muscle strength measured by hand held dynamometry and handgrip dynamometry from baseline to Week 12 •Change from baseline to Week 12 in the ALS Functional Rating Scale - Revised (ALSFRS-R) •Mean plasma concentrations over time of CK-2127107 at Week 12	Enrollment: 445 Age: 18 Years to 80 Years (Adult, Older Adult) Sex: All	•Cytokinetics •Astellas Pharma Inc	•Industry	Study Start: July 24, 2017 Primary Completion: March 2019 Study Completion: March 2019 First Posted: May 19, 2017 Results First Posted: No Results Posted Last Update Posted: August 1, 2018	•St. Joseph's Hospital and Medical Center - Barrow Neurological Clinics, Phoenix, Arizona, United States •Cedars-Sinai Medical Center, Los Angeles, California, United States •University of California Irvine, Orange, California, United States •Forbes Norris MDA/ALS Research Center, San Francisco, California, United States •Stanford Hospital and Clinics, Stanford, California, United States •University of Colorado Hospital Anschutz Outpatient Pavilion, Aurora, Colorado, United States •Hospital for Special Care, New Britain, Connecticut, United States •George Washington University Medical Faculty Associates, Washington, District of Columbia, United States •University of Florida, Gainesville, Florida, United States •Mayo Clinic, Jacksonville, Florida, United States •and 50 more

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
18	NCT03127514	AMX0035 in Patients With Amyotrophic Lateral Sclerosis (ALS) Study Documents:	Title Acronym: CENTAUR Other Ids: AMX-3500	Recruiting	•Amyotrophic Lateral Sclerosis •Motor Neuron Disease •Neuromuscular Diseases •Neurodegenerative Diseases •Spinal Cord Diseases •TDP-43 Proteinopathies •Nervous System Diseases •Central Nervous System Diseases	•Drug: AMX0035 •Other: Placebo	Study Type: Interventional Phase: Phase 2 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •ALSFRS-R Slope •Incidence of Adverse Events •Proportion of subjects in each group able to remain on study drug until planned discontinuation •Accurate Testing of Limb Isometric Strength (ATLIS) •Blood-based Biomarkers •Slow Vital Capacity •Survival, tracheostomy and hospitalizations •Imaging Biomarkers	Enrollment: 132 Age: 18 Years to 80 Years (Adult, Older Adult) Sex: All	•Amylyx Pharmaceuticals Inc. •ALS Finding a Cure Foundation •ALS Association •Northeast ALS Consortium •Massachusetts General Hospital Neurology Clinical Research Institute •Leandro P. Rizzuto Foundation	•Industry •Other	Study Start: June 22, 2017 Primary Completion: December 2018 Study Completion: May 2019 First Posted: April 25, 2017 Results First Posted: No Results Posted Last Update Posted: May 22, 2018	•Barrow Neurological Institute, Phoenix, Arizona, United States •UC Irvine Medical Center, Orange, California, United States •Forbes Norris MDA/ALS Research Center - California Pacific Medical Center, San Francisco, California, United States •University of Florida Medical Center, Gainesville, Florida, United States •Carol and Frank Morsini Center for Advanced Health Care - University of South Florida, Tampa, Florida, United States •Emory University Hospital, Atlanta, Georgia, United States •University of Iowa Hospitals and Clinics, Iowa City, Iowa, United States •University of Kentucky Medical Center, Lexington, Kentucky, United States •Ochsner Neuroscience Institute, New Orleans, Louisiana, United States •Johns Hopkins Hospital, Baltimore, Maryland, United States •and 15 more

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
19	NCT03095989	An Online Mindfulness Intervention for People With ALS and Their Caregivers Study Documents:	Title Acronym: Other Ids: IRB14-3695	Recruiting	•Amyotrophic Lateral Sclerosis	•Behavioral: Mindfulness	Study Type: Interventional Phase: Not Applicable Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Single (Outcomes Assessor) •Primary Purpose: Supportive Care Outcome Measures: •Quality of Life •Depression and anxiety •The patient's perception of physical impairment •Physician-assessed physical impairment •Vital capacity (VC) •Cognitive and behavioral function •Caregiver burden (caregivers only)	Enrollment: 100 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Harvard University •ALS Association •Milton S. Hershey Medical Center •Catholic University of the Sacred Heart	•Other	Study Start: January 2015 Primary Completion: December 2018 Study Completion: December 2018 First Posted: March 30, 2017 Results First Posted: No Results Posted Last Update Posted: March 29, 2018	•Penn State Hershey Medical Center, Hershey, Pennsylvania, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
20	NCT03068754	A Study to Assess the Efficacy and Safety of H.P. Acthar® Gel in the Treatment of Subjects With Amyotrophic Lateral Sclerosis Study Documents:	Title Acronym: Other Ids: MNK14042068	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: Acthar •Drug: Placebo	Study Type: Interventional Phase: Phase 2 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •Telephone administered Amyotrophic Lateral Sclerosis Functional Rating Scale Revised (ALSFRS-R) •Telephone administered ALSFRS-R total score decline •Investigator administered ALSFRS-R total score decline •Telephone administered ALSFRS-R total score and investigator administered ALSFRS-R total score •Pulmonary function test A: Mean slope of percent predicted forced vital capacity test •Pulmonary function test B: Mean slope of volume expired in 1 second test •Columbia-Suicide Severity Rating Scale (C-SSRS) •Telephone administered ALSFRS-R total score •Pulmonary function test A •Pulmonary function text B •Survival	Enrollment: 213 Age: 18 Years to 75 Years (Adult, Older Adult) Sex: All	•Mallinckrodt	•Industry	Study Start: June 14, 2017 Primary Completion: December 2019 Study Completion: December 2019 First Posted: March 3, 2017 Results First Posted: No Results Posted Last Update Posted: June 4, 2018	•Neuromuscular Research Center, Phoenix, Arizona, United States •Mayo Clinic - Arizona, Scottsdale, Arizona, United States •University of California San Diego, La Jolla, California, United States •Loma Linda University Health System, Department of Neurology, Loma Linda, California, United States •Keck School of Medicine, University of Southern California, Los Angeles, California, United States •University of California Los Angeles, Los Angeles, California, United States •University of California Irvine Medical Center, Orange, California, United States •California Pacific Medical Center, San Francisco, California, United States •University of California San Francisco, San Francisco, California, United States •Colorado Springs Neurological Associates, Colorado Springs, Colorado, United States •and 29 more

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
21	NCT03070119	Long-Term Evaluation of BIIB067 Study Documents:	Title Acronym: Other Ids: •233AS102 •2016-003225-41	Enrolling by invitation	•ALS Caused by Superoxide Dismutase 1 (SOD1) Mutation	•Drug: BIIB067	Study Type: Interventional Phase: Phase 1 Study Design: •Allocation: Non-Randomized •Intervention Model: Parallel Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •Number of participants experiencing AEs and serious adverse events (SAEs) •Number of participants with clinically significant laboratory assessment abnormalities •Number of participants with clinically significant vital sign abnormalities •Number of participants with clinically significant physical examination abnormalities •Number of participants with clinically significant neurological examination abnormalities •Number of participants with clinically significant 12-lead electrocardiograms (ECGs) abnormalities •PK parameter of BIIB067 in plasma: Maximum observed concentration (Cmax) •PK parameter of BIIB067 in cerebrospinal fluid (CSF): Cmax •PK parameter of BIIB067 in plasma: Time to reach the maximum observed concentration (Tmax) •PK parameter of BIIB067 in CSF: Tmax •and 6 more	Enrollment: 48 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Biogen •Ionis Pharmaceuticals, Inc.	•Industry	Study Start: March 8, 2017 Primary Completion: January 1, 2020 Study Completion: January 1, 2020 First Posted: March 3, 2017 Results First Posted: No Results Posted Last Update Posted: April 5, 2018	•Research Site, Phoenix, Arizona, United States •Research Site, La Jolla, California, United States •Research Site, San Francisco, California, United States •Research Site, Orlando, Florida, United States •Research Site, Atlanta, Georgia, United States •Research Site, Baltimore, Maryland, United States •Research Site, Boston, Massachusetts, United States •Research Site, Saint Louis, Missouri, United States •Research Site, Knoxville, Tennessee, United States •Research Site, Leuven, Belgium •and 4 more

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
22	NCT03049046	CC100: Phase 1 Multiple-Dose Safety and Tolerability in Subjects With ALS Study Documents:	Title Acronym: CC100B Other Ids: •CC100B •1R01FD004790-01	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: CC100 •Drug: Placebos	Study Type: Interventional Phase: Phase 1 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Double (Participant, Investigator) •Primary Purpose: Treatment Outcome Measures: •Safety and Tolerability: Adverse events, safety labs, vital signs, and ECGs •Pharmacokinetics (PK)--Peak plasma concentration (Cmax) •Pharmacokinetics (PK)--Area under the plasma concentration versus time curve (AUC) •Pharmacokinetics (PK)--Half life (T 1/2) •Pharmacodynamics (PD)--Monocyte chemotactic protein 1 (MCP-1) •Pharmacodynamics (PD)--Excitotoxicity/oxidative stress biomarkers	Enrollment: 21 Age: 18 Years to 64 Years (Adult) Sex: All	•Chemigen, LLC	•Industry	Study Start: April 7, 2017 Primary Completion: January 30, 2018 Study Completion: March 30, 2018 First Posted: February 9, 2017 Results First Posted: No Results Posted Last Update Posted: August 3, 2017	•Indiana University, IU Health Physicians Neurology, Indianapolis, Indiana, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
23	NCT03020797	A Clinical Trial to Evaluate the Safety and Efficacy of Fycompa in Subjects With Amyotrophic Lateral Sclerosis (ALS) Study Documents:	Title Acronym: Other Ids: Eisai-01	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: Perampanel •Drug: Placebo Oral Tablet	Study Type: Interventional Phase: Not Applicable Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •Incidence of treatment-emergent adverse events •Efficacy as measured by change in ALSFRS-R score (ALS functional rating scale-revised);	Enrollment: 60 Age: 18 Years to 80 Years (Adult, Older Adult) Sex: All	•Stony Brook University •Eisai Inc.	•Other •Industry	Study Start: December 2016 Primary Completion: December 2018 Study Completion: First Posted: January 13, 2017 Results First Posted: No Results Posted Last Update Posted: January 13, 2017	•Stony Brook University Medical Center, Stony Brook, New York, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
24	NCT02943850	CNS10-NPC-GDNF for the Treatment of ALS Study Documents:	Title Acronym: Other Ids: Pro00042350	Recruiting	•Amyotrophic Lateral Sclerosis	•Biological: Stem cell (HPC) implantation •Device: Stereotactic surgical device	Study Type: Interventional Phase: Phase 1 Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •Safety evaluated by Adverse Events and Serious Adverse Events, post-operative MRI, and clinical laboratory assessments •Compound Motor Action Potential (CMAP) •Force Generation via ATLIS testing •Quantitative Muscle MRI •Electrical Impedance Myography (EIM) •Assessment of glial cell line derived neurotrophic factor (GDNF) in the cerebral spianl fluid (CSF)	Enrollment: 18 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Cedars-Sinai Medical Center •California Institute for Regenerative Medicine	•Other	Study Start: April 1, 2017 Primary Completion: April 2019 Study Completion: April 2019 First Posted: October 25, 2016 Results First Posted: No Results Posted Last Update Posted: August 3, 2017	•Cedars-Sinai Medical Center, Los Angeles, California, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
25	NCT02872142	Efficacy and Safety of Plasma Exchange With Albutein® 5% in Patients With Amyotrophic Lateral Sclerosis Study Documents:	Title Acronym: Other Ids: GBI1501	Recruiting	•Amyotrophic Lateral Sclerosis	•Biological: Albutein 5%	Study Type: Interventional Phase: Phase 2 Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •Changes from baseline in the ALS Functional Rating Scale - Revised •Changes from baseline in forced vital capacity •Changes from baseline in cognitive function determined by the ALS - Cognitive Behavioral Screen test •Changes from baseline in the motor evoked potential in thenar and hypothenar eminence and anterior tibialis muscle determined by electromyography •Evaluation of quality of life using the ALS Assessment Questionnaire 40 •Changes from baseline in plasma human apolipoproteins •Changes from baseline in cerebrospinal fluid human apolipoproteins •Changes from baseline in plasma beta-methylamino-L-alanine levels •Changes from baseline in cerebrospinal fluid beta-methylamino-L-alanine levels •Changes from baseline in absolute leukocyte count •Changes from baseline in plasma neurofilament analysis •Changes from baseline in cerebrospinal fluid neurofilament analysis	Enrollment: 10 Age: 19 Years to 69 Years (Adult, Older Adult) Sex: All	•Grifols Therapeutics LLC •Grifols Biologicals Inc.	•Industry	Study Start: July 2016 Primary Completion: January 2019 Study Completion: January 2019 First Posted: August 19, 2016 Results First Posted: No Results Posted Last Update Posted: May 11, 2018	•Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
26	NCT02851914	SSRIs vs. TCAs for Depression in ALS Patients Study Documents:	Title Acronym: Other Ids: 22974	Recruiting	•Depression •Amyotrophic Lateral Sclerosis	•Drug: Tricyclic Antidepressants ("TCA") •Drug: Selective Serotonin Uptake Inhibitors ("SSRI")	Study Type: Interventional Phase: Early Phase 1 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •BDI-II •ANCOVA	Enrollment: 40 Age: 25 Years to 80 Years (Adult, Older Adult) Sex: All	•St. Louis University	•Other	Study Start: July 21, 2015 Primary Completion: December 2018 Study Completion: December 2018 First Posted: August 2, 2016 Results First Posted: No Results Posted Last Update Posted: February 12, 2018	•Monteleone Hall, Saint Louis University, 1438 South Grand Blvd., Saint Louis, Missouri, United States
27	NCT02750982	Laughter Therapy Effects on Mood, Stress and Self-efficacy in People With Neurological Diseases. Study Documents:	Title Acronym: Other Ids: TRBROWN201601	Recruiting	•Alzheimer's Disease •Amyotrophic Lateral Sclerosis •Brain Injury •Huntington's Disease •Multiple Sclerosis •Parkinson's Disease •Stroke •Spinal Cord Injury	•Other: Laughter Therapy	Study Type: Interventional Phase: Not Applicable Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Health Services Research Outcome Measures: •Patient Health Questionnaire (PHQ-9, for depression) •Generalized Anxiety Disorder 7-item scale (GAD-7, for anxiety) •The General Self-Efficacy Scale (GSE)	Enrollment: 24 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Brown, Theodore R., M.D., MPH	•Other	Study Start: July 2016 Primary Completion: August 2018 Study Completion: December 2018 First Posted: April 26, 2016 Results First Posted: No Results Posted Last Update Posted: January 23, 2018	•Evergreen Healthcare, Kirkland, Washington, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
28	NCT02682030	The Use of Airway Clearance Devices in ALS Study Documents:	Title Acronym: Other Ids: Pro00039699	Recruiting	•Amyotrophic Lateral Sclerosis	•Device: High Frequency Chest Compression Device (HFCC) •Device: Cough Assist	Study Type: Interventional Phase: Not Applicable Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •Change in Chest X-Ray between baseline and end of study •Change in Lung Ventilation Scan between baseline and end of study •Change in McGill Single item quality of life question between baseline and end of study •Change in Forced Vital Capacity (FVC) between baseline and end of study •Change in Maximal Inspiratory Pressure (MIP) between baseline and end of study •Change in Diffusion Capacity between baseline and end of study	Enrollment: 20 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Cedars-Sinai Medical Center	•Other	Study Start: March 2016 Primary Completion: December 2018 Study Completion: December 2018 First Posted: February 15, 2016 Results First Posted: No Results Posted Last Update Posted: April 5, 2018	•Cedars-Sinai Medical Center, Los Angeles, California, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
29	NCT02655614	A Study of GDC-0134 to Determine Initial Safety, Tolerability, and Pharmacokinetic Parameters in Participants With Amyotrophic Lateral Sclerosis Study Documents:	Title Acronym: Other Ids: •GN29823 •2017-002931-41	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: GDC-0134 •Drug: Placebo •Drug: Rabeprazole •Drug: Midazolam •Drug: Caffeine	Study Type: Interventional Phase: Phase 1 Study Design: •Allocation: Randomized •Intervention Model: Sequential Assignment •Masking: Double (Participant, Investigator) •Primary Purpose: Treatment Outcome Measures: •Percentage of Participants With Adverse Events (AEs) •Percentage of Participants With Clinically Significant Laboratory Abnormalities •Percentage of Participants With Clinically Significant Vital Signs Abnormalities •Percentage of Participants With Clinically Significant Electrocardiogram (ECG) Abnormalities •Percentage of Participants With Clinically Significant Abnormalities in Physical Examination Findings •Maximum Plasma Concentration (Cmax) of GDC-0134 •Time to Maximum Plasma Concentration (tmax) of GDC-0134 •Area Under the Plasma Concentration Versus Time Curve (AUC) of GDC-0134 •Apparent Clearance (CL/F) of GDC-0134 •Apparent Terminal Volume of Distribution (Vz/F) of GDC-0134 •and 9 more	Enrollment: 82 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Genentech, Inc.	•Industry	Study Start: May 31, 2016 Primary Completion: October 29, 2019 Study Completion: October 29, 2019 First Posted: January 14, 2016 Results First Posted: No Results Posted Last Update Posted: July 19, 2018	•Forbes Norris Mda/als Ctr; Research Center, San Francisco, California, United States •Mayo Clinic Hospital - Florida, Jacksonville, Florida, United States •University of Miami Miller School of Medicine, Miami, Florida, United States •Bioclinica Research, Orlando, Florida, United States •The Emory ALS Clinic, Atlanta, Georgia, United States •Johns Hopkins University School of Medicine, Baltimore, Maryland, United States •Massachusetts General Hospital, Boston, Massachusetts, United States •Wake Research Associates, Raleigh, North Carolina, United States •New Orleans Center for Clinical Research, Knoxville, Tennessee, United States •Methodist Neurological Institute, Houston, Texas, United States •MUCH - Montreal Neurological Institute & Hospital, Montreal, Quebec, Canada •UMC Utrecht, Utrecht, Netherlands

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
30	NCT02623699	Single and Multiple Dose Study of BIIB067 in Adults With Amyotrophic Lateral Sclerosis (ALS) Study Documents:	Title Acronym: Other Ids: •233AS101 •2015-004098-33	Recruiting	•Amyotrophic Lateral Sclerosis	•Drug: BIIB067 •Other: Placebo	Study Type: Interventional Phase: Phase 1 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •Number of participants experiencing Adverse Events (AEs) and Serious Adverse Events (SAEs) •Number of participants with clinically significant laboratory assessment abnormalities •Number of participants with clinically significant vital sign abnormalities •Number of participants with clinically significant physical examination abnormalities •Number of participants with clinically significant neurological examination abnormalities •Number of participants with clinically significant 12-lead electrocardiograms (ECGs) abnormalities •PK parameter of BIIB067 in plasma: Maximum observed concentration (Cmax) •PK parameter of BIIB067 in plasma: Time to reach maximum observed concentration (Tmax) •PK parameter of BIIB067 in plasma: Area under the concentration-time curve from time zero to infinity (AUCinf) •PK parameter of BIIB067 in plasma: Area under the concentration-time curve from time zero to the time of the last measurable concentration (AUClast)	Enrollment: 84 Age: 18 Years and older (Adult, Older Adult) Sex: All	•Biogen •Ionis Pharmaceuticals, Inc.	•Industry	Study Start: January 31, 2016 Primary Completion: February 2, 2019 Study Completion: February 2, 2019 First Posted: December 8, 2015 Results First Posted: No Results Posted Last Update Posted: June 1, 2018	•Barrow Neurological Institute, Phoenix, Arizona, United States •University of California San Diego Medical Center, La Jolla, California, United States •California Pacific Medical Center, San Francisco, California, United States •Compass Research, LLC, Orlando, Florida, United States •The Emory Clinic, Atlanta, Georgia, United States •Johns Hopkins Hospital, Baltimore, Maryland, United States •Massachusetts General Hospital, MA, Boston, Massachusetts, United States •Washington University School of Medicine, Saint Louis, Missouri, United States •Volunteer Research Group, LLC, Knoxville, Tennessee, United States •UZ Leuven, Leuven, Belgium •and 7 more

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
31	NCT02469675	Brain and Nerve Stimulation for Hand Muscles in Spinal Cord Injury and ALS Study Documents:	Title Acronym: Other Ids: HAR-15-001	Recruiting	•Spinal Cord Injury (SCI) •Amyotrophic Lateral Sclerosis (ALS)	•Device: Transcranial magnetic stimulation •Device: Median nerve stimulation •Device: Cervical transcutaneous stimulation	Study Type: Interventional Phase: Not Applicable Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Basic Science Outcome Measures: •Change in motor evoked potential (MEP) amplitude of the abductor pollicis brevis (APB) muscle response to single pulses of TMS •Hand dexterity •Safety and tolerability •Grip strength •Change in the duration of the 'cortical silent period' after TMS stimulation during APB contraction •F-wave responses of the APB muscle	Enrollment: 30 Age: 21 Years to 65 Years (Adult, Older Adult) Sex: All	•Bronx VA Medical Center	•U.S. Fed	Study Start: June 2015 Primary Completion: March 31, 2018 Study Completion: March 31, 2018 First Posted: June 11, 2015 Results First Posted: No Results Posted Last Update Posted: January 30, 2018	•James J. Peters VA Medical Center, Bronx, NY, Bronx, New York, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
32	NCT02437110	HERV-K Suppression Using Antiretroviral Therapy in Volunteers With Amyotrophic Lateral Sclerosis (ALS) Study Documents:	Title Acronym: Other Ids: •150126 •15-N-0126	Enrolling by invitation	•Amyotrophic Lateral Sclerosis	•Drug: Darunavir •Drug: Ritonavir •Drug: Raltegravir •Drug: Zidovudine	Study Type: Interventional Phase: Phase 1 Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Treatment Outcome Measures: •The proportion of participants with an undetectable HERV-K gag RNA level by quantitative PCR within 24 weeks of starting an antiretroviral regimen of darunavir, ritonavir, raltegravir, and zidovudine •Safety and feasibility of up to 24 weeks of darunavir, ritonavir, raltegravir, and zidovudine for patients with ALS •The proportion of participants with an undetectable HERV-K env or pol RNA level by quantitative PCR within 24 weeks of starting an antiretroviral regimen of darunavir, ritonavir, raltegravir, and zidovudine	Enrollment: 20 Age: 18 Years and older (Adult, Older Adult) Sex: All	•National Institute of Neurological Disorders and Stroke (NINDS) •National Institutes of Health Clinical Center (CC)	•NIH	Study Start: April 23, 2015 Primary Completion: December 31, 2018 Study Completion: December 31, 2018 First Posted: May 7, 2015 Results First Posted: No Results Posted Last Update Posted: February 14, 2018	•National Institutes of Health Clinical Center, 9000 Rockville Pike, Bethesda, Maryland, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
33	NCT02118727	Therapy in Amyotrophic Lateral Sclerosis With Memantine at 20 mg BID (TAME) Study Documents:	Title Acronym: TAME Other Ids: •TAME-ALS FD003937-01 •FDA	Not yet recruiting	•Amyotrophic Lateral Sclerosis •Frontal Temporal Dementia	•Drug: Memantine •Drug: Placebo (for Memantine)	Study Type: Interventional Phase: Phase 2 Study Design: •Allocation: Randomized •Intervention Model: Parallel Assignment •Masking: Quadruple (Participant, Care Provider, Investigator, Outcomes Assessor) •Primary Purpose: Treatment Outcome Measures: •Disease progression as measured by the number of points lost on the ALS Functional Rating-Scale-Revised (ALSFRS-R) •Measuring the levels of Tau, pNFH and the pNFH/ C3 ratio in CSF and blood	Enrollment: 90 Age: 18 Years to 85 Years (Adult, Older Adult) Sex: All	•University of Kansas Medical Center	•Other	Study Start: March 2018 Primary Completion: October 2021 Study Completion: October 2021 First Posted: April 21, 2014 Results First Posted: No Results Posted Last Update Posted: February 21, 2018	•Phoenix Neurological Associates, Phoenix, Arizona, United States •UC Irvine, Irvine, California, United States •University of Kansas Medical Center, Kansas City, Kansas, United States •University of Washington, Seattle, Washington, United States

	NCT Number	Title	Other Names	Status	Conditions	Interventions	Characteristics	Population	Sponsor/ Collaborators	Funder Type	Dates	Locations
34	NCT00912041	BrainGate2: Feasibility Study of an Intracortical Neural Interface System for Persons With Tetraplegia Study Documents:	Title Acronym: BrainGate2 Other Ids: •MGH-BG2-TP-001 •R01DC009899 •1UH2NS095548	Recruiting	•Tetraplegia •Spinal Cord Injuries •Amyotrophic Lateral Sclerosis •Brain Stem Infarctions •Locked in Syndrome •Muscular Dystrophy	•Device: Placement of the BrainGate2 sensor(s) into the motor-related cortex	Study Type: Interventional Phase: Not Applicable Study Design: •Intervention Model: Single Group Assignment •Masking: None (Open Label) •Primary Purpose: Other Outcome Measures: •The primary endpoint of this Study is to determine the safety of the BrainGate2 Neural Interface System. •To investigate the feasibility of BrainGate2 and to establish the parameters for a larger clinical study, such as appropriate neural decoding algorithms, sample size, indices of measurement, success criteria, and endpoints.	Enrollment: 15 Age: 18 Years to 75 Years (Adult, Older Adult) Sex: All	•Leigh R. Hochberg, MD, PhD. •National Institute on Deafness and Other Communication Disorders (NIDCD) •VA Office of Research and Development •National Institute of Neurological Disorders and Stroke (NINDS) •Massachusetts General Hospital	•Other •NIH •U.S. Fed	Study Start: May 2009 Primary Completion: September 2021 Study Completion: December 2021 First Posted: June 3, 2009 Results First Posted: No Results Posted Last Update Posted: March 29, 2018	•Stanford University School of Medicine, Stanford, California, United States •Massachusetts General Hospital, Boston, Massachusetts, United States •Case Western Reserve University, Cleveland, Ohio, United States •Providence VA Medical Center, Providence, Rhode Island, United States