Dear Friends,

2017 brings us another new year of providing the best possible comprehensive care for our patients and their families.

Clinical Research is one of the tools we use for comprehensive, integrated patient care. We are searching for the mechanism of ALS, with the goal of slowing or stopping disease progression. Many of our current studies include trials of various drug therapies targeted at specific areas affected by ALS; device trials; studies on the genetics of ALS; and searches for possible biomarkers.

I invite you to partner with me in continuing to sustain this extraordinary and essential patient care program into the future.

Regards,

Dale J. Lange, M.D.
Director, ALS program at Hospital for Special Surgery

HSS’s Annual Neuromuscular Disease Research Benefit on Friday, May 5th, 2017 at The Plaza in NYC

Don’t miss out! Check out our Gala & Silent Auction Website to learn about our research program, bid on auction items and pledge your support!

WWW.HSSNEUROLOGY2017.COM

Interested in attending? Contact Mona Shahbazi (shahbazim@hss.edu) or Shara Holzberg (Holzbergs@hss.edu) for more details!

Meet Your Team

Hebatallah Rashed, MD

Hello, I’m the new fellow, Dr. Hebatallah Rashed. I joined the team few months ago as the neuromuscular fellow, focusing on neuromuscular disorders and electrodiagnostic studies. My research interests include motor neuron disease and the use of magnetic stimulation in the diagnosis and treatment of various neuropsychiatric disorders. In my free time, I enjoy hiking, listening to music and styling. I look forward to working with you all at HSS.
Dale J. Lange, MD, neurologist-in-chief at Hospital for Special Surgery (HSS) and a professor of Neurology at Weill Cornell Medicine, has received the Diamond Award from the Muscular Dystrophy Association (MDA). The recognition is granted to a scientific leader dedicated to the eradication of amyotrophic lateral sclerosis, also known as ALS and Lou Gehrig’s Disease. Dr. Lange was honored at the 16th annual Wings Over Wall Street® event to benefit the MDA on October 27, 2016 in New York City.

“I am honored to receive this prestigious award,” said Dr. Lange. “Those honored in the past have been true giants in the field of ALS research and patient care, and it is truly humbling to be in their company.”

As medical director of the MDA/ALS Program at HSS, Dr. Lange oversees a multidisciplinary team of professionals devoted to caring for patients and their families with ALS. “Our skilled and compassionate team of healthcare professionals have expertise in dealing with any issues that patients and their families will encounter,” he noted.

Dr. Lange has been engaged in clinical and basic science research to improve the lives of people with ALS throughout his career. He has written more than 110 peer-reviewed articles and chapters in textbooks. He has been invited to lecture, both nationally and internationally, on topics related to his research in neuromuscular disease. He served as president of the New York State Neurological Society in 2011 and 2012.

“MDA is proud to honor Dr. Lange with the 2016 Wings Over Wall Street Diamond Award for his dedication to the individuals impacted by ALS. His commitment to care and research continues to drive the lifesaving mission for a future free of ALS,” said Bonnie Fuchs, director of Business Development at the MDA.

“Over the past 20 years, there have been significant strides in our understanding and treatment of ALS,” Dr. Lange noted. “Unfortunately, we are still searching for the cure, but we have learned so much about the molecular changes that occur in the cells affected by ALS, that most investigators in the field firmly believe we are close to finding new ways to slow or stop the progression of this disease. In the meantime, our clinical care of patients has shown significant advances. Multidisciplinary programs, such as the one at Hospital for Special Surgery, have enabled us to prolong and improve the quality of life of people with ALS.”
Former San Francisco 49ers’ star Dwight Clark is the latest pro football player to be diagnosed with ALS. Which leads to the question: Is there a connection between head trauma suffered by pro football players and the degenerative disease? Dr. Dale J. Lange, neurologist-in-chief at HSS and current president of the New York State Neurological Society, was consulted for insight into a crippling disorder that, in the past year, claimed the lives of former NFL players Mickey Marvin and Kevin Turner and that seems to affect a greater percentage of football players than it does the general population.

**Q: What defines ALS, and how is it diagnosed?**

**DR. LANGE:** ALS is a pretty easy diagnosis to make, but the point is that it’s a clinical diagnosis. There is only one situation where we can unequivocally make a diagnosis with ALS, and that is when it’s inherited. About 10 percent of PALS have an inherited disease with a known mutation. There are several different mutations, but we know that in about 60 to 70 percent of the people with inherited disease, we can identify that mutation. Once we identify the mutation in the appropriate person with weakness we know the diagnosis … and it really can’t be anything else.

In the vast majority of patients that have ALS — and I don’t know anything about Mr. Clark’s family history, but if I extrapolate his condition to the other football players or sports players who have had this disease — most of them are non-familial ALS.

We make the diagnosis through a couple of fairly but not totally unique clinical features: you have progressive weakness and wasting of muscle in multiple levels of the nervous system. So that would be arms, legs, breathing, speaking and swallowing. Our level of confidence increases when we have weakness, wasting and muscle twitching in multiple segments of the nervous system because ALS is a complete motor system disease. It affects the brain’s contribution to the motor system, as well as the spinal cord’s contribution. The combination of weakness, wasting and twitching, plus over-reactive reflex actions kind of makes the clinical diagnosis of ALS. Once you have those, it’s incumbent upon the clinician to make sure that there are no other potential causes that can mimic this illness. And there are very few. Long story short: It is a clinical diagnosis.

There are no diagnostic markers. Those of us in the research world are trying desperately to find a marker for this disease to help us be sure of the diagnosis, but we don’t have it yet.

**Q: Given your involvement in clinical and science research, what advantages in the treatment of ALS have been made in the last 10 years?**

**DR. LANGE:** I think we divide it into two segments. One is the advance in treating people with the familial disease, and that’s one area that we are very excited about because we have a cause. I think if we can hit that one, we can extrapolate to the sporadic disease. If we can silence the genes that we know or somehow make the products of those mutations less toxic, we think we’re on our way to mitigating the progression or even stopping the illness, which we can do in animals. Those treatments are actually in clinical trials now, and we’re excited about that. To say that repeated head trauma is a cause of ALS overstates our knowledge. But to say that it is associated with ALS is true.

**Q: So there have been successes?**

**DR. LANGE:** It’s too early. The trials are probably within a year of getting started, so I can’t say that. But the basis of the trials are the strongest that we’ve ever had. The scientific basis and the rationale are extraordinarily strong. We’re very excited about the possibility of slowing patients with inherited diseases — either slowing or stopping that syndrome. We’re making extraordinary advances in treating genetic diseases. Over the last two years we’ve made remarkable changes in being able to delete mutations. Depending upon the degree, in familial ALS, we’re using genetic tools to silence abnormal genes, and we think it really should make a difference in stopping the disease so it’s not really long term.

In (treating) sporadic disease we’ve had a couple of really interesting findings — probably the most interesting is the use of stem cells. Stem-cell therapy in ALS in sporadic disease is giving us some very interesting and exciting signals that may well also cause a slowing of the disorder.

**Q: A 2012 study concluded that pro football players are four times as likely to die from ALS or Alzheimer’s disease as the general public. Is it true?**

**DR. LANGE:** The only data that we really have is the article that you quote and there is some pathophysiology to support that. I think to say that repeated head trauma is a cause of ALS overstates our knowledge. But to say that it is associated with ALS is true.

There are articles in the 80s and 90s, if I’m remember correctly, that previous head trauma was always statistically significantly more in patients with ALS. And, so, if you look at previous history, head trauma would stand out as being, not 90 percent, but more than the control group. Once chronic traumatic encephalopathy (CTE) was identified by the people in Pittsburgh and followed up by the people in Boston, we were able to try to connect the two. And I think it’s making a story that makes sense — although we can’t prove it yet — that the findings that are induced by repeated trauma causes problems with the brain that may predispose people to particular forms of dementia, as well as ALS. The exact mechanism is unclear, but there certainly are interesting hypothetical scenarios that would suggest that the interruption of the neurons in the brain causes an impairment of metabolic flow in the neurons, inducing a situation that may lead the nerve to accumulate toxic proteins.

One of the things that we know is that both in ALS and dementia there are accumulations of what we call aggregates that are found in the neurons of people with CTE, as well as ALS and regular Alzheimer’s. And those aggregates are now thought to be instrumental in the propagation of the disease, which is really what we’re talking about — basically, that the neurons die. So that’s how, at the present time, we’re connecting the two events. And I think we all believe there’s a connection. It’s just not a cause and effect. There are loads of people who have repeated head trauma who don’t develop dementia and who don’t develop ALS, but certainly it is one of the risk factors for you to develop one of those two degenerative diseases.

**Q: So while there’s no direct correlation between concussions and ALS, there is an increased risk of incurring the disease if you’ve suffered repeated head trauma?**

**DR. LANGE:** That’s our understanding now. There’s no question that people who have repeated concussions are more susceptible … however you define concussions — (maybe more like) repeated head trauma, but I’m not so sure concussions are the sine qua non of this. Then you have to have a threshold. (So) is it: You can’t get hit more than 20 times? (What about) the increased prevalence in soccer players? Is it because of the head trauma that they do with the ball? I think we’re at a point where we know repeated concussive or head trauma … and the quantity is not known … will predispose the brain to chronic traumatic encephalopathy, and those findings can evolve into either dementia, ALS or both.

**Q: Athletes generally are in superior physical condition to the general public. Does that superior condition help them in managing the symptoms of ALS once they’re affected?**

**DR. LANGE:** The interesting question is: Does their superior physical condition put them at any increased risk of developing ALS? And I just posed that. There’s no strong data for and against it. There’s been a big debate in the neurological community as to whether or not aggressive exercise … or exercise in any sort of way … is a risk factor for ALS. One of the features that we all have seen is that ALS is relatively uncommon in very under active, obese (patients). It’s not unheard of. But the better condition you’re in, it seems to the clinician that (that individual) will make up the majority of your practice rather than the person who is not in condition and is moderately obese and doesn’t take care of himself.

Adapted from article by Judge Clark on Sports Network http://www.talkoffamenetwork.com/dwight-clark-als-and-what-the-future-holds-for-both/
Department of Neurology Offers Patients Virtual Appointment Options

Providing quality patient care and experience is a priority across all departments at HSS. Earlier this year, the Department of Neurology began implementing new technology to make care more accessible and convenient through TeleHealth, a web-based telemedicine portal that allows HSS physicians to conduct virtual appointments with patients.

According to Dale J. Lange, MD, Chairman of Neurology and Neurologist-in-Chief, TeleHealth works just like Skype or FaceTime, but in a HIPAA compliant network that ensures safety and security of patient information. Patients can make a formal appointment, but instead of coming to HSS to see a physician, the appointment is conducted virtually.

“Many of our patients find it difficult to come to HSS because of weakness,” said Dr. Lange. “TeleHealth enables us to visit real-time and address urgent and non-urgent needs without waiting for appointments.”

TeleHealth provides a perfect venue to conduct a virtual appointment and observe the patient. We are able to obtain an interactive history and form a thorough analysis of language and movement. With TeleHealth, physicians can now see the quizzical look on a patient’s face or observe their body language while speaking with them.

To date, more than 10 patient encounters have taken place via TeleHealth. The patients who have used the technology have been extremely pleased with the results. They feel as though they are having a personal visit with their treatment team in their own home. It is convenient and easy, especially for those who live far away from HSS or have difficulty traveling into Manhattan.

“This gives us a different option, and now it has become part of my routine to give patients the option to follow up with me to discuss lab results, care management or answer questions,” said Dr. Lange. “Many people come from far away to see us for our diagnostic expertise. There is not always a need to have an in-person visit when a face-to-face TeleHealth visit would suffice.”

TeleHealth puts HSS at the forefront of a national shift toward providing patients with high-quality, convenient virtual care options in addition to the traditional ways that we deliver care. Dr. Lange sees telemedicine expanding in the department and in medicine in general, becoming integrated throughout other departments across HSS.

Recent studies have shown about 40% of follow-up care typically provided by neurologists can be conducted remotely through video-based telehealth. Telemedicine for neurology has made it possible to offer convenient, routine follow-ups for all patients. 98-percent of patients using teleneurology are just as satisfied with remote care as they are with in-person care.

95-percent of Neurology patients who begin receiving remote follow-up care want to continue it.
TASTE OF SPRING
By Jessica Cording, MS, RD, CDN

As the weather warms up, spring is the perfect time for frozen desserts. Check out these cheerful, dysphagia-friendly recipes to welcome the new season.

**Watermelon Gazpacho**

*Total Time: 20 minutes
*Servings: 10 cups

**Ingredients:**
- 1 ripe avocado (good source of healthy fats and fiber)
- 1 red bell pepper, stemmed, seeded, diced
- 1 ear of corn, roasted, cut off the cob
- 1 pound (455 g) seedless watermelon, cubed
- 2½ pounds (1.1 kg) red heirloom tomatoes, diced
- 1 pound (455 g) english cucumber, peeled, quartered
- 1 chipotle in adobo sauce, seeded, diced
- 2 teaspoons chipotle in adobo sauce, seeded, diced

**Directions:**
Roast the red bell pepper over an open flame until blackened. Put into a paper bag for 5 minutes then peel off charred skin and remove seeds and stem. Roast corn over flame, turning frequently until the corn is charred. Roughly chop the roasted red pepper and cut the corn off the cob. Combine in a large-size bowl with the watermelon, tomatoes, and cucumber. Add the chipotle, adobo sauce, scallions, garlic, lime juice, cilantro, olive oil, kosher salt and lightly mix.

Transfer the mixture in batches to the Vitamix container and secure lid. Select Variable 1. Turn machine on and slowly increase speed to Variable 10, then to High. Blend or 30 seconds. Transfer to a pitcher and thoroughly chill.

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**5-Ingredient Mint Ice Cream**

*Hands-on Time: 5 minutes
*Freezing Time: 1 hour
*Total Time: 1 hour, 5 minutes
*Servings: 2

**Ingredients:**
- 1 ripe avocado (peeled, good source of heart-healthy fats and fiber)
- 2 frozen bananas (unpeeled)
- 2 tablespoons fresh mint, chopped (or 1 teaspoon mint extract)
- 1/4 teaspoon vanilla extract
- 1 tablespoon sweetener of choice (maple syrup, honey, stevia, etc.)

**Directions:**
Pulse ingredients in a food processor until smooth. Pour into a re-sealable container and freeze for an hour. Remove ice cream from freezer and use an ice cream scoop to divide between two cups. Garnish with mint leaves. Variations: Blend in cocoa powder or chocolate chips if desired. This is also delicious topped with whipped cream (or whipped coconut cream) and chocolate syrup.
Interested in Clinical Trials?

ClinicalTrials.gov is a website with information on federally and privately funded studies across a wide range of diseases and conditions. It was made available to the public in February 2000 and is maintained by the National Library of Medicine and National Institutes of Health. The primary purpose was to create a searchable database with information about current ongoing clinical research studies. Due to changes in policies and laws, the website has developed over the years. For instance, in September 2008 the site expanded to include a results database. In September 2016, penalties for failing to register or submit results of trials were enforced. Therefore, investigators and sponsors must publish information on study outcomes including adverse events. ClinicalTrials.Gov is currently the largest clinical trials database with over 230,000 trials from 198 countries.

Getting Started

The first dropdown on the homepage is titled “Find Studies.” You can use the “Basic Search” or “Advanced Search” option. The “Basic Search” will provide you with a wide range of results. For example, if you type “amyotrophic lateral sclerosis” a list of 369 studies populates. These include active (green) and completed studies (red). The active studies indicate whether or not they are recruiting. The completed studies indicate whether or not there are results. We recommend using the “Advanced Search” option to come up with more targeted options. By entering “Condition” and “State” you can find 55 studies for ALS in the tri-state area. You can also add the Principal Investigator’s name (e.g. Lange), drug name (e.g. Ezogabine), or keyword (e.g. brainstorm). The “modify this search” button at the top of the page allows you to easily make changes. If you have any questions on how to search, how to find results, or how to read a study record, detailed instructions are included on the website: https://clinicaltrials.gov/

Next Steps

While we offer a number of clinical trials at HSS, you should stay informed about additional trials you might qualify for. Start by reviewing the inclusion/exclusion criteria. If you meet criteria then reach out to the appropriate contact. Before a screening visit can be scheduled, the study coordinator may request your medical records. You can also ask for a copy of the Informed Consent. This is a legal document with detailed information about the study procedures, risks and benefits, possible costs and alternative procedures. In most cases, information about studies is also available on the hospital’s website. However, ClinicalTrials.gov is a great starting point for patients looking to get involved in research.
HSS Staff Showcases Their Research Projects

Every year, the MND Association organizes the International Symposium on ALS/MND. This International Symposium is the largest medical and scientific conference on MND/ALS. It is the premier event in the MND research calendar, attracting over 1,000 delegates, representing the energy and dynamism of the global MND research community. For more information and highlights of what was presented at the 2016 annual meeting, please visit their website at: https://www.mndassociation.org/research/international-symposium/

A few members of our team attended this annual conference and had the opportunity to present some research projects on which they have been working. A brief summary of their work is listed below:

**Pantelis Pavlakis MD, PhD**  
Patterns of disease progression in SOD1 familial motor ALS: a retrospective study of 42 patients with long-term follow-up.  
SOD1 mutations are the second most common genetic cause of motor neuron disease. In this study we followed 42 patients over a course of 9 months and described their clinical course and disease progression. The study showed that there is variability in the clinical presentation and disease course among patients with different mutations.

**Melissa Kaiser, RN**  
A Retrospective Study of Patients Diagnosed with Amyotrophic Lateral Sclerosis and Concurrent Cases of Thrombi  
A review of the 141 charts of patients with ALS in our clinic revealed that 11.3% developed at least one thrombo-embolic event since symptom onset. This is consistent with previous studies [Gladman et al.’s (2014)] that suggest a risk of 11.2%.

**Gioia Ciani, OTD, OTR/L & Shara Holzberg, MS, CCC-SLP**  
Driving forces behind driving habits and driving cessation in patients with ALS.  
While driving involves a high degree of motor and cognitive abilities, for most people, it provides freedom and autonomy. This study looked at possible reasons surrounding PALS decisions to practice or cease driving when aware that progressive loss of motor function or cognitive function can impact their ability to drive safely. Data collection is still ongoing, but preliminary analysis suggest that 80% of those surveyed have changed their driving habits over the past 6 months.

**Megan Parmenter, CCRP**  
Application of Neuropsychological Measures for Patients with ALS  
This study examines the effectiveness of neuropsychological assessments in measuring mild cognitive impairment in patients with ALS. Preliminary analysis suggest that the HVLT-R and D-KEFS can be used to measure executive and non-executive function, including memory and verbal fluency, in patients with ALS. MMSE lacks sensitivity and is not recommended for use in this patient population.
**What Is A Clinical Trial? Why Are They Necessary?**

Clinical trials are the best method researchers have developed not only to find effective treatments, but to weed out useless or harmful treatments. The search for new therapies usually begins in a lab. New potential treatments are tested in cell cultures or animal models. This is critical for showing whether a potential treatment has any merit at all.

**What Types of Trials Are Available?**

- **Phase I** trial is when a drug is given to a small number of people to see if it is safe in humans. Small sample size is intentional in order to expose as few people as possible to an untried treatment. Phase I trial is critical to determine safety. While a Phase I trial may also begin to test whether a drug is effective in treating a disease, this is not its main purpose, and any positive results can only be considered tentative.

- **Phase II** trial is when a drug that is safe can be initially tested for effectiveness. A sample size of 30 and 50 people is typical. Most Phase II trials test the drug against a placebo—an inactive substance that looks and tastes like the drug being tested but has no effect on the disease the new drug is intended to treat. If the drug continues to appear safe, and shows some signs of effectiveness, it will be tested in the next phase, Phase III.

- **Phase III** trial is considered the definitive test of whether a drug is effective. It is always a placebo-controlled trial, and enrolls many more patients than a phase II trial. It is usually conducted by multiple researchers at multiple different sites around the country or even around the world. A treatment that succeeds in a Phase III trial is considered to be truly effective and can be submitted by the drug company to the FDA for permission to market the drug for treatment of that particular disease.

**What is a Placebo-Controlled Trial?**

A placebo-controlled trial is a trial in which there are two (or more) groups. A placebo is an inactive substance that looks and tastes like the drug being tested but has no effect on the disease the new drug is intended to treat. One group gets the active treatment, the other gets the placebo. Everything else is held the same between the two groups, so that any difference in their outcome can be attributed to the active treatment.

**What does double-blind mean?**

In a double-blind trial, neither the researchers nor the research participants know who is getting active medication and who is getting placebo. In this way, their hope of benefit from the real treatment will not affect the results. A monitoring group not involved in the study randomly assigns patients to one group or the other, and keeps track of the group assignments during the trial. At the end of the trial, the “blind is broken,” and the researchers and patients find out who received active treatment.

**If I enter the placebo arm, can I get the active drug later?**

Yes, if the treatment does provide benefit then anyone in the trial can continue to receive it after the trial. It is critical to offer treatment to those who have contributed so much to the research by joining the trial.

*Please see the HSS Research Brochure attached for what is happening now at HSS. For more information regarding accessing additional trials around the world, please see page 6.*
FAQs ABOUT CLINICAL RESEARCH TRIALS

Why bother with a double-blind, placebo-controlled trial. Why can’t they just make it available now for everyone?

The double-blind, placebo-controlled trial is considered the “gold standard” for clinical trials. It has the best chance of determining whether an active treatment is effective. This is true for several important reasons:

1) Because no one knows if they are receiving active treatment, the chances are reduced that any benefit seen will be due to the placebo effect.

2) With some diseases, like ALS, the population is a diverse group. One important way in which they differ is in the speed of progression of their illness: some people progress slowly, while others, unfortunately, progress more quickly. By randomly assigning subjects to active treatment and placebo groups, that diversity is spread equally between the groups. This increases the chances that any benefit seen will be due to differences in treatment, rather than differences in the patients in each group.

Fastest Way To Develop New Treatments

Testing new drugs in studies designed to give the answer quickly and without doubt is only possible by comparing the active treatment (new therapy) with a placebo. Two recent ALS clinical trials show how important double-blind, placebo-controlled trials are in weeding out ineffective treatments:

- An open-label trial of lithium in a small number of PALS suggested this drug helped slow the disease.

But a larger, placebo-controlled, double-blind trial found no effect. Without that trial, many PALS may have gone on to take a useless medication.

- Animal studies and open-label human trials suggested the antibiotic minocycline was beneficial. But a larger, placebo-controlled trial showed it was not, and may even have been harmful. Without that larger trial, patients may have continued taking minocycline, causing harmful effects without helping their disease.

Only with placebo-controlled trials could these two treatments be ruled out as ineffective, saving PALS from taking medicines that offer no benefit and that could even be dangerous. It’s important to remember......experimental drugs are indeed experimental. Meaning that the drug can have a positive effect, no effect at all, or be detrimental. It is sometimes difficult to keep in mind that someone on a placebo may actually be getting better treatment than someone on the active medication. While a trial with a negative result is very disappointing to both participants and study organizers, every trial teaches us something valuable and makes subsequent trials more likely to succeed. The negative trial results only strengthens our commitment to finding truly beneficial treatments for ALS. That work can only succeed if patients enroll in clinical trials.

Check out our current and upcoming trials below. GET INVOLVED! Contact Shara, Megan, Aisha or Mona with inquiries.

GET INVOLVED!!!! Contact Shara, Megan, Aisha or Mona with any questions.

AS SEEN ON TV!!!

Dr. Lange pairs up with representatives from MDA for a segment on abc7 to discuss muscle disease and research! Segment was aired on the LI Viewpoint news station with host Eyewitness News anchor Ken Rosato.
If you are looking to make charitable donations, please consider giving to the Neuromuscular Disease Research Fund. We are dedicated to finding answers, treatments and therapies for neuromuscular disease. Our program is largely built based on support of donors. Your support gives us the foundation to provide the best patient care under the direction of leaders in the field in a multidisciplinary care model. Please join in the fight and help us to continue to fund the research that will hopefully lead to effective treatments and possible cures for neuromuscular diseases.

Does your company have a gift matching program? Many employers sponsor gift matching gift programs and will match any charitable contributions made by their employees. If you’d like to set-up a matching gift to the Neuromuscular Disease Research Fund, talk to your HR Department or contact Douglas Williams at 212-606-1046 or WilliamsDou@hss.edu to make a donation.

Meet Your Clinic Team

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