Welcome

Welcome to the Winter 2013 edition of the M.U.S.C.L.E. Group Newsletter. We at the Medical University of South Carolina LUPUS Erythematosus Research Group are working extremely hard to identify causes and better treatments for Systemic Lupus Erythematosus. We are pleased to have had the opportunity of working with patients with lupus, their families, and friends over the years. It is because of you that we are able to do what we do.

We hope that this newsletter is both informative and motivating in regards to the fight against lupus.

Tips for Managing Your Lupus

- **Exercise Regularly** – Simple exercise 20-30 minutes a day, 5 days a week (walking, swimming, stretching, etc.) can help reduce stress, maintain heart health, improve muscle strength, and help prevent osteoporosis.

- **Get Enough Rest** – Rest helps damaged or inflamed muscles and tissues heal and also reduces fatigue. At least 7-8 hours of sleep per night is optimal.

- **Eat Healthy** – A nutritious and well-balanced diet, including fruits and vegetables, is great for your health. It is also important for lupus patients to limit their sugar, salt, saturated and trans-fat intake.

About Lupus

Lupus is a chronic autoimmune disease in which the immune system creates antibodies against "self" cells. This leads to tissue destruction and inflammation in virtually any organ in the body.

There is currently no cure for lupus, but medications do exist to treat the symptoms of the disease. Benlysta® is the first drug in over 50 years to have been approved by the FDA for treatment in lupus patients.

An estimated 1.5 million Americans and at least 5 million people worldwide have a form of lupus. It’s up to researchers like us here at MUSC to do all that we can to find better treatments and, ultimately, a cure for lupus.
**Lupus Questions**

**Answered by the Doctors of MUSCLE**

**Features of Lupus**

**Q:** Is there a specific test to diagnose lupus?

**A:** The ANA, or anti-nuclear antibody, test is positive in almost all cases of lupus. If the test comes back negative it is very unlikely you have lupus. If the test is positive, there are a number of diseases that can cause a positive ANA as well as 10-20% of healthy individuals can have borderline positive testing. There are a couple of other blood tests that are relatively specific for lupus, but positivity in these tests does not make the diagnosis of lupus. Lab tests help confirm the physician’s diagnosis which is made on the symptoms and physical exam of the patient.

**Q:** Are there any reported cases of lupus in remission?

**A:** Lupus rarely goes into complete remission where the patient has no symptoms and is on no medication. Most patients are well controlled with medication, but the disease is still present.

**Lupus Flares**

**Q:** What are the common causes of lupus flares?

**A:** Ultraviolet light, infection, certain antibiotics (sulfa and tetracyclines), hormones, and possibly extreme stress.

**Medications**

**Q:** How can I get approval from my insurance company for new treatments like Rituxan & Benlysta?

**A:** Your doctor must file paperwork indicating the need for treatment. For Rituxan, your doctor must prove that it is medically necessary and for Benlysta there are set criteria a patient must meet to get the drug.

**Q:** How long should it take to start feeling the effects of Benlysta?

**A:** It normally takes between 1 and 3 months.

**Other Therapies**

**Q:** Can this condition be treated with vitamins or herbal supplements?

**A:** Vitamin D is gaining increasing interest as a possible treatment for lupus. You can ask to have your vitamin D level checked to see if you are deficient.

**Q:** Are there any vaccinations I should or should not have?

**A:** Lupus patients should NOT take live vaccines, such as the intranasal flu vaccine, typhoid, adenovirus, rotavirus, smallpox, and yellow fever. The CDC recommends you SHOULD get the yearly flu vaccine (non-nasal) and the pneumococcal vaccine.

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**Getting Involved in the Fight Against Lupus!**

- **Register for a Walk to End Lupus**
  [www.lupus.org](http://www.lupus.org)

- **Participate in Lupus Awareness Month in May**
  [www.lupusawarenessmonth.org](http://www.lupusawarenessmonth.org)

- **Join a Lupus Foundation of America Chapter**
  [www.lupus.org](http://www.lupus.org)

**The MUSCLE Team**

**MUSCLE Investigators**

- Diane Kamen, MD, MSCR
- Gary Gilkeson, MD
- James Oates, MD
- Holly Mitchell, MD
- Natasha Ruth, MD, MSCR
- Hazel Breland, PhD
- Edith Williams, PhD, MS
- Melissa Cunningham, MD

**MUSCLE Study Coordinators**

- Stephanie Slan
- Maggie Harding
- Colleen Reed
- Barbara Roe
- Abigail Powell
- Carol Lambourne

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The MUSCLE Newsletter is going electronic! If you would like to continue to receive this Newsletter, please send your email address to lupusresearch@musc.edu
Current Clinical Research Studies in Lupus at MUSC

Determinants of Travel Burden among Patients with SLE

Telemedicine, eHealth, and mHealth (mobile) aspects have expanded in the past ten years, yet very little research has been conducted to determine whether SLE patients, rheumatologists treating SLE patients, and family members / caregivers of SLE patients desire telemedicine. This research area has great promise for the SLE cohort at MUSC because a large number of the patients commute over 30 miles for their Rheumatology visits, and could improve inequitable healthcare accessibility issues experienced by SLE patients. Perspectives from patients, rheumatologists and family members / caregivers will be determined from the use of surveys administered to participants in the study.

For more information, contact Kasim Ortiz at 912-506-6698

Registry for Biologics in SLE

This is a registry for patients with SLE who are seen by physicians at MUSC and have recently started a biologic therapy as a part of their routine care. Questionnaire information will be gathered at entry into the study, 3 months, 6 months, and then yearly for 10 years or until the biologic therapy is discontinued (whichever comes first). This is a multi-site study and will have up to 2,000 participants total.

For more information, contact Maggie Harding 843-792-8613

Vitamin D to Improve Endothelial Function in Lupus Patients

This study is looking at Vitamin D and cardiovascular function in lupus patients who have low vitamin D levels. In this study, we expect to screen 50 or more participants for vitamin D deficiency by drawing blood by vein (up to 10 ml or two teaspoons). Of the first 32 screened who are vitamin D deficient, we will randomize (assign by chance) 16 patients to receive either a low, non-replenishing dose (400 units (IU) daily) and 16 patients to receive a high, replenishing dose of vitamin D (5,000 IU daily) after measuring their blood vessel endothelial function by flow mediated dilation (FMD) and performing a history, physical examination, blood draw (up to 60 ml or 4 tablespoons), and urine collection. FMD is measured by putting an ultrasound probe (like a microphone with some jelly on top) on a blood vessel in the arm. Measures are taken before and after a blood pressure cuff is inflated on the arm to cut off blood supply for five minutes and then several minutes after release. After patients have taken vitamin D for 16 weeks, we will measure FMD again to determine if endothelial function improves on the higher dose of vitamin D. We will perform a history and physical and draw blood (up to 60 ml or 4 tablespoons) and collect urine to determine mechanisms through which vitamin D might be improving vascular function.

For more information, contact Abby Powell at 843-792-4095

SLE In Gullah Health (SLEIGH)

SLEIGH is an observational study enrolling African Americans from the Sea Island communities of South Carolina and Georgia. We are enrolling patients, family members of patients, and unrelated community members. The main purpose of this study is to find genes that, along with factors from the environment, result in the development of SLE. Volunteers in SLEIGH will be asked to answer questions about their health and have blood and urine collected for tests. After the first visit there may be one additional visit 2 or more years later. This is not a drug study.

For more information, contact Stephanie Slan at 843-792-8997

Belimumab in SLE

The purpose of this trial is to determine if belimumab is a safe and effective treatment for adults who have SLE. Qualified participants will be assigned to either placebo or belimumab. Study participation may last approximately 60 weeks, including follow-up, with the option to continue in an open enrollment study. Study participants will receive study-related health examinations at no cost. Compensation for time and travel may also be available.

For more information, contact Barbara Roe at 843-792-6864

Subcutaneous LY2127399 in SLE

The purpose of this research trial is to determine if the study drug LY2127399, is a safe and effective treatment for adults (men or women) ages 18 and older who have SLE. This study is sponsored by Eli Lilly and will be conducted on the MUSC campus at the Clinical Translational and Research Center (CTRC). Each qualified participant will be assigned to either placebo (non-study drug) or LY2127399 (study drug). Study participation may last approximately 2 years, including follow-up. Study participants will receive study-related health examinations at no cost and compensation for time and travel may also be available.

For more information, contact Barbara Roe at 843-792-6864

Thank you for participating in Lupus research studies!

DV1179 in SLE

The purpose of this study is to investigate the safety of an investigational drug (DV1179) for the treatment of systemic lupus erythematosus (SLE) in adults with SLE. Knowledge gained from this study may help to further develop this potentially beneficial therapy for patients with SLE.

For more information, contact Abby Powell at 843-792-4095
Save the Date!

Lupus Listening and Learning Group “Balancing Your Body Chemistry” Presented in two parts by Dr. Diane Kamen

Monday, January 14, 2013
5:45 pm – 7:30 pm at Mt. Pleasant Presbyterian Church, Grace Hall Room 123
-Will focus on challenges lupus adds to maintaining basic health

Saturday, February 2, 2013
10:30 am – 12:15 pm at Hampton Inn, Charleston – North
-Will focus more specifically on body changes caused by lupus, managing medications, and the importance of monitoring labs

Contact Alice Burress at 843-884-3949 with questions

The Systemic Lupus International Collaborating Clinics Cohort Study of Atherosclerosis in SLE

Patients with SLE are known to develop coronary artery disease at a higher rate and earlier age than the general population. As a result of these changes, patients with SLE are at an increased risk of developing problems such as heart attacks and angina up to five times more frequently. The purpose of this study is to collect information on a large number of newly diagnosed SLE patients followed by SLICC researchers, and to follow these patients over time.

For more information, contact Abby Powell at 843-792-4095

Thank you for participating in Lupus research studies!

For a full up-to-date listing of clinical research studies being conducted at MUSC, please visit the ScResearch.org website.

Belimumab + Standard of Care vs. Placebo + Standard of Care in Lupus Nephritis

Interventional Drug Trial: The purpose of this trial is to determine the efficacy and safety of belimumab in the treatment of lupus nephritis for adults. Each qualified participant will be assigned to either placebo plus standard of care medication or belimumab plus standard of care medication. Study participation may last approximately 2 years, including follow-up. Study participants will receive study-related health examinations at no cost and compensation for time and travel may also be available.

For more information, contact Maggie Harding at 843-792-8613

Lupus Foundation of America’s 2012 List of Achievements in Lupus Research

1. New Rallying Cry Engages Public to Join the Fight to End Lupus
The LFA launched a new campaign this year to rally the public around support for lupus research with the rallying cry, “Help Us Solve the Cruel Mystery™.”

2. US House of Representatives Establishes Congressional Lupus Caucus
The LFA hopes that this caucus will increase support for lupus research.

3. World’s Largest Lupus Walk Raised Record-Breaking Funds
Close to 67,000 people in over 60 US cities walked to raise more than $5 million for lupus research and awareness.

4. Revised Classification Criteria for Lupus
The SLICC (Systemic Lupus International Collaborating Clinics) organization updates the classification criteria for diagnosing lupus.

5. New Lupus Test Improves Diagnosis Accuracy
A new test has been developed by Exagen Diagnostics, Inc. which allows physicians to more quickly and accurately diagnose lupus.
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RETURN SERVICE REQUESTED

Email your questions or concerns to us at:
lupusresearch@musc.edu
Visit our website at: www.musc.edu/lupus
Call us at: 1-866-859-6107

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