



LUPUS NEWS

Participating in Clinical Trials *by Elena Massarotti, MD*

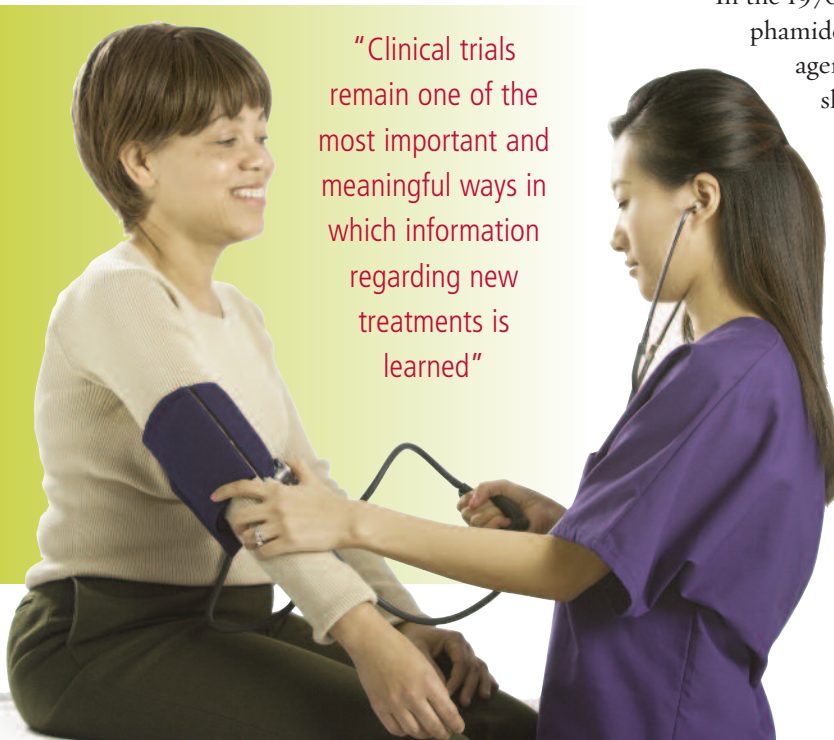
The Lupus Center at the Brigham and Women's Hospital (BWH) is committed to providing all lupus patients with state of the art clinical care. The delivery of this care is in parallel with commitments to the advancement of medical research, and medical education. Like many academic teaching hospitals, lupus patients obtaining their care at the BWH may receive care from physicians and nurses in training, and may also be asked to participate in helping to teach medical students about many different aspects of lupus. These educational programs help insure the future growth of clinically astute physicians and are an essential component of the overall mission of the BWH.

BWH is dedicated to furthering medical research underlying the cause of all diseases, and providing patients with newer and improved therapies. In research, an "investigator" attempts to answer a specific question that remains unanswered. Examples of "research questions" might be: "Does sun exposure trigger lupus flares?" or "Does high blood pressure lead to an increased risk of stroke?" Researchers try to answer these research questions in many different ways—by reviewing

medical records, interviewing patients, or examining "databases" that contain specific medical information about the patient's illness. A very common research question involves determining if a specific medication or treatment safely and effectively treats a condition or illness. An example of this type of research question might be "Is antibiotic A more effective than antibiotic B in treating pneumonia?" Often times, answers to questions regarding whether a medication is effective for a particular illness is best addressed in a *clinical trial*, where individuals are "enrolled" in a study comparing treatments. Depending upon the study, and the question being asked, a clinical trial may compare one drug with another, or with a placebo. Clinical trials remain one of the most important and meaningful ways in which information regarding new treatments is learned. Knowledge regarding the benefits of hydroxychloroquine (also known by the trade name, Plaquenil) in preventing lupus flares was determined in a clinical trial of lupus patients published in 1991. The results of this trial provided the foundation for the recommendation that treatment with hydroxychloroquine be considered for all lupus patients. In the 1970s, a major clinical trial comparing cyclophosphamide (CTX) with steroids and other chemotherapy

agents for the treatment of lupus related kidney disease showed that patients treated with CTX had improved kidney function compared with the other regimens used. In the last several years, several clinical trials comparing mycophenolate mofetil (MMF or Cellcept) with CTX for the treatment of lupus related kidney disease have shown that MMF may be as effective as CTX for treating kidney disease and associated with fewer side effects than CTX. The results of these trials help inform the decisions that rheumatologists and

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"Clinical trials remain one of the most important and meaningful ways in which information regarding new treatments is learned"

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patients must make together in deciding which treatment is best for a patient's particular problem.

For any research that involves patients—even if the research involves reviewing medical charts without actually speaking with patients—there are mechanisms in place to assure that the research is conducted ethically and safely. *Institutional Review Boards* (IRBs) are composed of individuals trained in research ethics. In addition to “approving” a research program prior to its start, the IRB also monitors ongoing research activity to assure that the clinical trial or study is proceeding properly. These IRBs are composed of health care professionals (doctors, nurses, pharmacists, scientists) as well as lay members of the public. No research of *any kind* involving patients may proceed without IRB approval. The BWH has a very active IRB that meets several times a month.

When an investigator decides to conduct a clinical trial, the research proposal presented to the IRB must contain very specific information about how patients are invited to participate. The decision to participate is entirely voluntary, and a patient's decision to NOT participate will in no way affect the patient's care at BWH. A discussion regarding the study or trial takes place between the patient and the investigator or a member of the research team. During these discussions, the patient is encouraged to ask questions regarding the research and to take as much time as needed to decide to participate or not. The patient can also discuss the trial with the primary care doctor, friends and family. A “consent form” that details the purpose of the study, how it will be done, and the potential risks and benefits of participation is provided and reviewed together with the investigator; this consent form must be signed by the patient and the investigator (or representative) and only then can the research begin.

The duration of a clinical trial may range from a onetime visit, to multiple visits over extended periods of time depending upon how the study is designed. The time commitment required to complete a trial is an important consideration for patients, especially for patients who have other time constraints or responsibilities

like work, or family. Compensation for travel to come to the research center to participate in the voluntary research, or for the time required to participate in the research is commonly provided. It is very expensive to conduct a clinical trial. The costs of conducting a trial are related to personnel needed to do the research, the laboratory tests and other materials required to properly monitor the study, the medications being tested, and administration. Funding sources include private foundations like the Lupus Foundation of America, the federal government (National Institutes of Health) and the pharmaceutical industry. The BWH may also fund independent research.

Over the last decades, the investigators in the Lupus Center at the BWH have conducted numerous clinical trials in patients with lupus seen at the BWH and elsewhere. In 1968, Dr. Peter Schur, Emeritus Clinical Director of the Lupus Center at BWH, determined in a clinical trial that measurements of double stranded DNA (dsDNA) and complement were helpful in determining if a patient's lupus was “active”. This study, which was published in the *New England Journal of Medicine*, led to improved disease management and continues to inform clinical decision making today. Dr. Karen Costenbader, Associate Director of the Lupus Center, developed a new “index” used to measure the “damage” that lupus or its treatment has caused among patients with lupus. This index is an important measurement of the effects of lupus. Dr. Bonnie Bernas, Director of the Lupus Center, is currently studying pregnancy outcomes in lupus patients seen at the BWH over the last decade. Over the last several years, Dr. Elena Massarotti has conducted several clinical trials of medications for the treatment of lupus. One study examined the effects of two different doses of vitamin D upon an immunologic feature of lupus (the interferon signature) in lupus patients with vitamin D levels less than 20____. The results of this study showed that repleting vitamin D in lupus patients did not affect the levels of this immunological aspect of lupus. Other clinical trials conducted by investigators in the Lupus Center at BWH over the last years include a study of rituximab in

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Social Media

Dawn Peters (right) and Kelley Keefe are patients at the Lupus Center. They have been a part of the Lupus Center's Patient Advisory Board for the last 4 years now. Recently, they discussed the importance of mentoring for both old and new lupus patients. However, they realized that in-person mentoring can sometimes be difficult given the disabling symptoms of Lupus. This led them to start Facebook and Twitter accounts using the name “Lupus Ladies”, that allow them to interact with other patients who are living life with lupus or other autoimmune diseases online. Their profile information states, “Lupus Ladies connects those living with lupus and other autoimmune diseases by sharing personal experiences and important health-related information. Together we can support each other as we live life with chronic illness.”



Like the Lupus Ladies on Facebook (www.facebook.com/LupusLadies) or follow @lupusladies on Twitter.

Award Spotlight

Candace Feldman, MD, MPH,

a second year rheumatology fellow, has been selected as LFA's first ever Career Development Award grantee.



She will be starting a research project on infectious diseases associated with different immunosuppressive medications used for SLE and lupus nephritis, in July 2013. Dr. Karen Costenbader is her research mentor.

May A. Aldaabi, MD

Dr. Aldaabi is a Rheumatologist. She attained her medical degree in Saudi Arabia and was awarded a scholarship from the Saudi Ministry of Higher Education to pursue Internal Medicine and Rheumatology training at the University of British Columbia, Canada. Currently, her research involves studying the progression of patients who initially presented with possible Lupus and looking into predictors of their evolution and outcome. Her other research interests include the epidemiology and etiology of lupus disease and treatment.



Bonnie L. Bermas, MD

A member of the BWH Division of Rheumatology for 19 years, Dr. Bonnie Bermas has been the Director of the BWH Lupus Center since 2005. Says Dr. Bermas, “ People often ask me how I got interested in rheumatology and in particular lupus. While I knew since I was five that I wanted to become a doctor, it wasn’t until I was a resident in internal medicine that I decided on rheumatology. Intellectually, I found the complexity of the clinical diseases in conjunction with the immune basis of rheumatologic disorders fascinating. Professionally, I knew that I wanted to care for patients with chronic disorders so that I could develop long term relationships with patients and their families. I’ve never looked back, I still enjoy coming to work each day and I still am excited about the new areas of understanding of lupus and new treatments”



In addition to seeing patients and the administrative responsibilities of the center, Dr. Bermas is a co-investigator on some of Dr. Massarotti’s clinical trials and Dr. Costenbader clinical studies. Currently Dr. Bermas is working with one of the third year medical residents on a project on lupus and pregnancy. This area is one of particular interest to Dr. Bermas, as she lectures and writes extensively on the area of pregnancy and rheumatic diseases. We asked Dr. Bermas what is her vision of the lupus center for the upcoming year. “ I look forward to expanding our clinical trials and clinical research programs. I am excited about some new collaborations with basic sciences and pharmaceutical industry. I am grateful to our patient advisory board for bringing us up to the 21st century of social media with their patient oriented facebook page and twitter account. And of course, I hope that we continue to improve our care of our lupus patients so that they can live meaningful and healthy lives.”

Norma Padua

The next time you see your Rheumatologist at BWH, you may get the opportunity to meet Norma Padua, a medical assistant in the Lupus Center. Norma completed her medical assistant training with the American Red Cross and has been working at Brigham and Women’s Hospital for over a year now.



For Norma, her favorite part of her job is working with patients. “Whether it’s taking a patient’s vital signs, just listening to them if they need someone to talk to, or holding their hand while their doctor is doing a procedure, at the end of the day I love knowing that I am helping someone,” she says. Her best recollections are of sick patients who come back for follow-up appointments with drastic improvements in their health. Norma’s advice to her patients is always “to never get discouraged and never give up.”

ONGOING BWH LUPUS CENTER RESEARCH STUDIES

Ets-1 Protein Study – Previous studies have shown that the lack of Ets-1 protein may be associated with active lupus. Dr I-Cheng Ho and colleagues at BWH are studying the relationship between Ets-1 protein and lupus. You may be eligible to take part in this study if you are an adult and have active lupus. This study involves a blood draw, and can be done at the time of your doctor’s visit. If you are interested to learn more about this study, please contact the study coordinator, Jade Cumberbatch, at nhcumberbatch@partners.org or 617-732-5354

BLISS SC Study – Dr Massarotti is currently enrolling eligible individuals with active lupus for this study of a self injectable form of belimumab (also known as Benlysta). Lupus patients with “active” disease (meaning that the lupus is not controlled) but not involving the kidneys or brain might be able to participate. Dr Massarotti and her team can provide more information regarding this study (Coordinator: Jade Cumberbatch (nhcumberbatch@partners.org; 617-732-5354).

Biomarkers of Lupus Activity – This study is a research collaboration between physicians and researchers at BWH and researchers at Pfizer, Inc., a company that is hoping to develop a new drug to treat lupus. To be eligible, you must be a pre-menopausal woman who is at least 18 years old and have a diagnosis of systemic lupus erythematosus. At normally scheduled rheumatologist appointments, participants will be asked to complete a questionnaire and give a one-time blood sample at the same time as their routine blood work. For more information, contact Tabatha at 617-525-8785 or e-mail at tlorton@partners.org. (IRB # 2012P002497)

2013 Calendar of Events from the Lupus Foundation of New England

The Lupus Foundation of New England is an organization that helps people and families affected by lupus. It provides resources for education and support. It also helps to fund lupus research with other organizations. (www.lupusne.org)

Wednesday, May 1, 2013

Alex and Ani Charmed by Charity Event
Alex and Ani Wayland Square
Providence, RI

Saturday, May 18, 2013

Unlocking the Mystery of Lupus
East Providence City Hall
East Providence, RI

Saturday, June 1, 2013

2nd Annual Lupus Rhode Island Walk
Slater Park, Pawtucket, RI

Saturday, June 29, 2013

Elks #2285 Motorcycle Charity Run
The Coventry, West Greenwich, RI

Saturday, September 7, 2013

Lupus: Learning and Living™
Lupus Foundation of America
Sheraton Hotel

Sunday, September 8, 2013

21st Annual Lupus Walk on the Charles
Artesani Park, Brighton, MA

Thursday, October 24, 2013

5th Annual Runway for a Cure
Providence Biltmore, Providence, RI

November, 2013

Boston Lupus Pub Crawl
Bell in Hand Tavern
Boston, MA

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lupus patients with lupus related kidney disease, and another “biologic” medication (atacept) for lupus patients who have active symptoms. The rituximab kidney study showed that rituximab added to mycophenolate mofetil did not result in a better outcome than those patients treated with mycophenolate mofetil alone. The results of the atacept trial haven not yet been fully analyzed. At this time, there are several ongoing clinical trials for lupus patients at BWH. Two studies involve the use of belimumab for lupus; belimumab was FDA approved for lupus in 2011 and is given intravenously. One study compares a self injectable form of belimumab with placebo for patients with active lupus. Another belimumab study at BWH compares intravenous belimumab with placebo in lupus patients of African American descent.

Clinical trials provide important information regarding the potential risks and benefits of new treatments. These trials require a commitment of time and effort for the patient, can be costly, and are monitored closely by institutional review boards. In 2011, the combined efforts of patients and investigators in clinical trials resulted in the first FDA approved drug for lupus in over forty years—belimumab. Our hope for all patients with lupus is that continued research will lead to more and improved treatment choices for patients, and ultimately, a cure for lupus.

If you are interested in learning more about the lupus center or supporting our research and educational programs please call Andrea Rattan (617) 732-5515 or visit our website www.brighamandwomens.org/rheumatology/lupus/

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