S.L.E. Lupus Foundation List of New York- Area Clinical Trials

Manhattan:

**Memory and Thinking Difficulties in Lupus**
Sponsor: National Institutes of Health
Seeking Volunteers: People with lupus to attend a total of five visits over a period of two years. Involves assessment of medical history and general health, physical examination, and selected laboratory tests. Computerized tests will measure attention, memory and problem solving ability. The goal is to determine a connection between cognitive dysfunction (thinking difficulties) and ethnic background in people with SLE.
Contact: Research staff of Dr. Melanie Harrison 212-606-1867

Manhattan:

**Lupus Immunosuppressive/Immunomodulatory Therapy or Stem Cell Transplant (LIST)**
Sponsor: National Institute of Health/NIAID
Seeking Volunteers: Persons between the ages of 18 and 60 with severe lupus who are taking corticosteroids to control their disease, along with other major lupus drugs, and have at least one of the following conditions of severe steroid-refractory disease: lupus nephritis, other visceral organ involvement, or a cytopenia (reduction in the number of blood cells) that is immune-mediated.
Contact: Julissa Diaz at Columbia University at 212-342-2216 or email jmd202@columbia.edu

Manhattan:

**Antiphospholipid Syndrome Collaborative Registry (APSCORE)**
Sponsor: National Institutes of Health/NIAMS
Seeking Volunteers: People with antiphospholipid antibodies to join a national disease registry.
Contact: Gail Buxton: 919-966-0572; 800-411-1222; or email apscore@med.unc.edu

Manhattan:

**Treating Systemic Lupus Erythematosus (SLE) Patients with CTLA4-IgG4m (RG2077)**
Sponsor: National Institute of Allergy and Infectious Diseases (NIAID), Immune Tolerance Network
Seeking Volunteers: Persons age 18 and above with lupus nephritis. Also, people with SLE and on concurrent treatment with intravenous cyclophosphamide for certain manifestations of lupus. Also: stable medication regimen for at least 4 weeks prior to study entry, weight between 88.2 lb and 275.6 lb, and willing to use acceptable forms of contraception.
Contact: 212-305-9986
Manhattan:

**A Study to Evaluate the Safety and Effectiveness of Edratide in the Treatment of Lupus (Phase II)**
Sponsor: Teva Neuroscience
Seeking Volunteers: Men and women between ages 18 and 65 years who fulfill at least 4 criteria for SLE.
Contact: Shared Solutions 1-866-550-0614.

Manhattan:

**The Research Registry for Neonatal Lupus**
Sponsor: National Institute of Arthritis and Musculoskeletal and Skin Diseases
Seeking Volunteers: Mothers with antibodies to SSA/Ro, SSB/La, or RNP, or child of mother with such antibodies who has neonatal lupus, or father of neonatal lupus-affected child or maternal grandparents of neonatal lupus-affected child or aunts and uncles of neonatal lupus-affected child.
Contact: Peg Katholi at 212-598-6514; peg.katholi@nyumc.org

Manhattan:

**Triptorelin for Ovary Protection in Childhood Onset Lupus**
Sponsor: FDA Office of Orphan Products Development
Seeking Volunteers: Females between ages 9 and 21 years, not pregnant, who have lupus and are newly requiring IV cyclophosphamide.
Contact: Hermine Brunner, MD. 513-636-7275; hermine.brunner@cchmc.org

Manhattan:

**New Drug That May Protect Function of Reproductive Organs in Girls Receiving Cyclophosphamide for Lupus**
Sponsor: FDA Office of Orphan Products Development
Seeking Volunteers: Females who have been diagnosed with Systemic Lupus Erythematosus, are younger than 21 years of age, and require intravenous cyclophosphamide to control the disease.
Contact: Lisa F Imundo, MD 212-305-9304; lfi1@columbia.edu

Manhattan:

**Predictors of Pregnancy Outcome in Systemic Lupus Erythematosus (SLE) and Antiphospholipid Syndrome (APS)**
Sponsors: Hospital for Special Surgery, NIAMS, Alliance for Lupus Research
Seeking Volunteers: Pregnant women who will be grouped and analyzed according to the presence or absence of aPL antibodies and preexisting SLE.
Contact: Silvia H. Norbis, AB  212-606-1214; norbiss@hss.edu
Marta M Guerra, AB, MS  212-774-7361; guerram@hss.edu

Manhattan:

Memory and Attention Problems in Lupus: New Treatment Trial with Modafinil
Sponsor: Hospital for Special Surgery
Seeking Volunteers: SLE patients at the Hospital for Special Surgery with functional
cdifficulties due to cognitive dysfunction.
Contact: Daniel M Horn, BA  212-606-1867; hornd@hss.edu
Claudia M. Reuben, BS 212-606-1867; reubenc@hss.edu

Health-Related Quality of Life Measure in Pediatric Lupus
Sponsors: University of Medicine and Dentistry New Jersey, Hospital for Special Surgery, New York, St. Barnabas Medical Center, Hackensack University Medical Center, La Rabida Children's Hospital, Pfizer
Seeking Volunteers: Children ages 2 through 18 with SLE.
Contact: Lakshmi N Moorthy, MD, MS  732-235-4980  moorthln@umdnj.edu
Maria J Baratelli, BA  732-235-6555   baratemj@umdnj.edu

Manhattan:

Dexamethasone Treatment for Congenital Heart Block (CHB) in Newborns with Lupus
Sponsor: NIAMS
Seeking Volunteers: Mother must have anti-Ro and/or anti-La antibody, Fetal bradyarrhythmia (slow, abnormal heart rhythm)
Contact: Claudine Davis  212-598-6513   prideinchb@yahoo.com
Jill P. Buyon, MD  212-598-6522   jill.buyon@med.nyu.edu

Manhattan

Safety and Tolerability of MEDI-545 in Patients Who Have Mild Systemic Lupus Erythematosus (SLE) with Cutaneous Involvement
Sponsor: MedImmune, Inc
Seeking Volunteers: Persons 18 years or older with SLE and the presence of cutaneous (skin) lupus erythematosus and various cutaneous lesions, in addition to other criteria.
Contact: Lori Tam at Hospital for Special Surgery 212-774-7137
Kevin Rochford at Columbia University Medical Center 212-342-3655

Manhattan + Flushing + Lake Success + Rochester

Study of LJP 394 in Lupus Patients with History of Renal Disease
Sponsor: La Jolla Pharmaceutical Company
Seeking Volunteers: Persons between 12 and 70 years of age with diagnosis of SLE and active renal disease within the past 4 years, and ability to have weekly intravenous (IV) administration of study treatment.
Contact: In Flushing: Michael Schwenk, PharmD 718-670-2703
In Manhattan at NYU: Angelique Shriky 646-356-9413
In Manhattan at Columbia Presbyterian: Kevin Rochford 212-342-3655

Manhattan + Bronx + Syracuse:

Study of Epratuzumab in Systemic Lupus Erythematosus
A Phase III Multi-Center, OpenLable, Follow-Up Study to Assess the Safety & Efficacy of Epratuzumab in Patients with Acute Severe SLE Flares Excluding the Renal or Neurologic Systems
Sponsor: UCB
Seeking Volunteers: Persons 18 and above who have completed SL0003 Alleviate A through 48 weeks.
Contact: UCB Clinical Trial Call Center: 1-877-822-9493

Manhattan + Brooklyn + Lake Success + Syracuse

Abatacept in the Treatment and Prevention of Active Systemic Lupus Erythematosus (SLE) Flares in Combination with Prednisone
Sponsor: Bristol-Myers Squibb
Seeking Volunteers: Subjects must be diagnosed with SLE and be experiencing an active lupus flare in at least one of three organ systems: skin (discoid lesions), inflammation of the lining of the heart (pericarditis), or inflammation of the lining of the lung (pleuritis/pleurisy); or inflammation of more than 4 joints within 14 days of a screening visit and be on a stable dose of prednisone (<30mg) for at least one month.
Contact: BMS Call Center  1-866-892-1BMS  Ext. 175

Manhattan + Albany + Rochester

A Study to Evaluate the Efficacy and Safety of Rituximab in Patients with Severe Systemic Lupus Erythematosus (Phase II + Phase III)
Sponsor: Genentech
Seeking Volunteers: Men and women ages 16 – 75 with a lupus diagnosis and active disease.
Contact: Trial Information Support Line 888-662-6728.

Brooklyn + Manhattan + Lake Success

ALMS—Aspreva Lupus Management Study of Mycophenolate Mofetil (MMF) in Lupus Nephritis.
Sponsor: Aspreva Pharmaceuticals (as part of the Roche-Aspreva Collaboration Agreement)
Seeking Volunteers: Persons with a diagnosis of lupus nephritis requiring
immunosuppressive therapy.  
Contact: medinfo@aspreva.com

Bronx:

GL701 P(PrestaraTM) in Women with Systemic Lupus Erythematosus Receiving Treatment with Glucocorticoids (Phase III)  
Sponsor: Genelab Technologies  
Seeking Volunteers: Women age 18 and above who has completed the full 6 month treatment period with study drug in the previous clinical study of GL02-01.  
Contact: Betty Quarles, B.Sc. 650-562-1425; bquarles@genelabs.com

Stonybrook:

Plaquenil for Alopecia Areata, Alopecia Totalis  
Sponsor: Hordinsky, Maria K., MD  
Seeking Volunteers: Men and women age 18 and above with severe alopecia areata (hair loss) or complete baldness.  
Contact: Cathleen Boeck, RN 612-625-4973; boeck001@umn.edu  
Richard Kalish, MD, PhD 631-632-9036; Richard.kalish@sunysb.edu

Disclaimer

This information does not represent a S.L.E. Lupus Foundation endorsement of any listed study. It is merely a notice that the study is available. If you are presently under the care of a physician for lupus or other conditions, you should not disrupt your current program without discussing it with your doctor(s). Do not contact the S.L.E. Lupus Foundation for information on these studies. Only contact the listed numbers. The S.L.E. Lupus Foundation does not have any jurisdiction over or further involvement with these studies, other than to make people aware that they are being conducted.

Updated: October 2006